

IN THE COURT OF COMMON PLEAS
HAMILTON COUNTY, OHIO
CIVIL DIVISION

LOUISE BAYLISS, BY AND
THROUGH HER HUSBAND AND
NEXT FRIEND, STEVEN BAYLISS
36 Sheraton Court
Hamilton, Ohio 45013

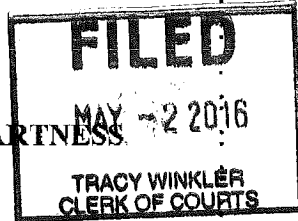
Case No. A 1 6 0 2 5 3 8

JUDGE

And

COMPLAINT
AND JURY DEMAND

KEVIN & HILLARY HARTNESS
605 Elm Street #1
Felicity, Ohio 45120



And

(ALL NEW DR. DURRANI
CASES SHALL GO TO JUDGE
RUEHLMAN PER HIS ORDER)

CAROLYN & WILLIAM HURSONG
3464 Hollyglen Court
Cincinnati, Ohio 45251

And

CHRISTOPHER MCCAUGHEY
As Administrator of the
ESTATE OF SARAH JUERGENS
727 Martin Luther King Dr. W. Apt 409w
Cincinnati, OH 45220

And

LINDA KALLMEYER-WARD
12000 Westerly Drive
Cincinnati, OH 45231

And

KATELYN KAUFFMAN
16 Merlin Drive
Fairfield, OH 45014

And

AMANDA KOCH
5133 Mount Alverno
Cincinnati, OH 45238

EXHIBIT A

And

RUVIMBO NYEMBA
4131 St. Martins Place
Cincinnati, OH 45211

And

RONALD ROWLEY
274 Prairie Avenue
Wilmington, OH 45177

And

BILLY SPIVY
310 Rice Drive #14
West Union, Ohio 45693

Plaintiffs,

v.

ABUBAKAR ATIQ DURRANI, M.D.,
Serve: Orthopedic & Spine Institute
203 Canal Road
Lahore 54000 Pakistan
(Serve by regular mail)

And

**CENTER FOR ADVANCED SPINE
TECHNOLOGIES, INC.**
Serve: Orthopedic & Spine Institute
203 Canal Road
Lahore 54000 Pakistan
(Serve by regular mail)

And

WEST CHESTER HOSPITAL, LLC
7700 UNIVERSITY DRIVE
WEST CHESTER, OH 45069
SERVE: GH&R BUSINESS SVCS., INC.
511 WALNUT STREET
1900 FIFTH THIRD CENTER
CINCINNATI, OH 45202

(Serve via Certified mail) :

And :

UC HEALTH :

SERVE: GH&R BUSINESS SVCS., INC. :

511 WALNUT STREET :

1900 FIFTH THIRD CENTER :

CINCINNATI, OH 45202 :

(Serve via Certified mail) :

And :

CHRIST HOSPITAL :

2139 AUBURN AVENUE :

CINCINNATI, OHIO 45219 :

SERVE: CT CORPORATION :

SYSTEM :

1300 EAST NINTH STEET :

CLEVELAND, OHIO 44144 :

And :

CINCINNATI CHILDREN'S :

HOSPITAL MEDICAL CENTER :

3333 BURNET AVENUE :

CINCINNATI, OH 45229 :

Serve: Frank C. Woodside III :

1900 Chemed Center :

Cincinnati, OH 45202 :

(Serve via Certified mail) :

Defendants. :

Come now Plaintiffs, and file this Complaint and jury demand, pursuant to the agreement of the parties and Order of the Court, and state as follows:

INTRODUCTORY PARAGRAPH

1. All of the Plaintiffs filed in this lawsuit are residents of and domiciled in the State of Ohio.
2. Plaintiffs have filed these cases together because of the common fact each of them had

- surgeries performed by Dr. Durrani while he was under suspension at West Chester Hospital.
3. Dr. Durrani, during his suspension from August 6, 2010 until October 5, 2010, performed surgeries on multiple Plaintiff's by labeling the surgeries "emergencies."
 4. Dr. Durrani performed more than 30 surgeries while he was under suspension at West Chester Hospital.
 5. A memorandum, attached as **Exhibit A**, discusses conversations that Brian Isaacs and Santen Hughes Law firm had, which addresses and confirms that Dr. Durrani was suspended from August 6, 2010 through at least October 5, 2010 at West Chester Hospital. **Exhibit B** is the list of cases subject to this Complaint allegation.
 6. The memorandum states, Dr. Durrani was suspended he was not allowed to schedule new patients or perform surgeries, etc.
 7. Plaintiffs, Louise Bayliss, Kevin Hartness, Carolyn Hursong, Sarah Juergens, Linda Kallmeyer-Ward, Ruyimbo Nyemba, and Billy Spivy, all have Infuse/BMP-2 implanted in their spines from surgeries Dr. Durrani performed while under suspension at West Chester Hospital.
 8. Plaintiffs Sherri Allen, Gayle Bachman, Gerald Botner, Latoya Bradshaw, Neil Favaron, Tonia McQueary, and Christina Brashear are also Plaintiffs that Dr. Durrani performed surgery on while he was under suspension at West Chester Hospital; however, these cases are already filed with this Court.
 9. Plaintiff Christina Goldstein is also a Plaintiff that Dr. Durrani performed surgery on while he was under suspension at West Chester Hospital; however, this case has already been filed in Butler County Court.
 10. Additionally, these cases are being filed together to be cost efficient as well as being filed

together for their common scheme of facts and based upon Judge Ruehlman's December 15 Court Order Plaintiffs will request ALL cases involving Dr. Durrani operating while suspended be tried together.

JURISDICTION AND VENUE

11. At all times relevant, Plaintiffs were residents of and domiciled in the State of Ohio.
12. At all times relevant, Defendant Dr. Abubakar Atiq Durrani (hereinafter "Dr. Durrani") was licensed to and did in fact practice medicine in the State of Ohio.
13. At all times relevant, Center for Advanced Spine Technologies, Inc. (hereinafter "CAST"), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.
14. At all times relevant, The Christ Hospital ("TCH") was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operating under the trade name The Christ Hospital.
15. At all times relevant, Cincinnati Children's Hospital Medical Center (hereinafter "Children's Hospital"), was authorized to transact business and perform medical services in the State of Ohio and operate under the trade name Children's Hospital Medical Center.
16. At all times relevant herein, Children's Hospital held itself out to the public, and specifically to Plaintiff, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.
17. At all times relevant, West Chester Hospital, LLC (hereinafter "West Chester Hospital"), was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

18. At all times relevant, Defendant UC Health Inc., was a duly licensed corporation which owned, operated and/or managed multiple hospitals including, but not limited to West Chester Hospital, and which shared certain services, profits, and liabilities of hospitals including West Chester.
19. At all times relevant herein, West Chester Medical Center, Inc., aka West Chester Hospital held itself out to the public, and specifically to Plaintiffs, as a hospital providing competent and qualified medical and nursing services, care and treatment by and through its physicians, physicians in training, residents, nurses, agents, ostensible agents, servants and/or employees.
20. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.
21. UC Health Stored BMP-2 at UC Health Business Center warehouse located in Hamilton County.
22. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC. UC Health is located in Hamilton County making Hamilton County appropriate to bring this lawsuit.
23. The amount in controversy exceeds the jurisdictional threshold of this Court.
24. These Plaintiffs cases have been previously dismissed pursuant to Civ. R. 41(A)(1)(a) and is now being refiled within the time allowed by O.R.C. 2305.19.

FACTUAL ALLEGATIONS OF PLAINTIFFS

LOUISE BAYLISS BY AND THROUGH HER HUSBAND AND NEXT FRIEND,

STEVEN BAYLISS

25. At all times relevant, Plaintiffs were married and residents and domiciled in the State of Ohio.
26. Plaintiff sought treatment with Dr. Durrani in September 2010, after a referral from her

family physician, Dr. Mital.

27. Dr. Durrani informed Plaintiff she had two bulging discs and a neck fracture and that surgery was necessary so that she would be pain free.
28. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.
29. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
30. On or about October 4, 2010, Dr. Durrani performed surgery on the Plaintiff at West Chester Hospital.
31. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.
32. The use of BMP-2 increases a person's chance of cancer by 3.5%
33. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
34. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
35. Following surgery, Plaintiff's voice was really deep and scratchy, but Dr. Durrani informed the family that this was temporary and that he had gone through the front of her neck as it was less invasive and quicker to heal.
36. On October 6, 2010, Mrs. Bayliss was sent to Schroeder Manor for one week of rehab, which surprised the family. Plaintiff was in extreme pain and could not walk on her own

without the assistance of a cane or walker.

37. On October 18, 2010, Plaintiff had a post-operative visit and expressed pain and discomfort.

38. Over the next several months, Mrs. Bayliss was in constant pain, monitored by family. Mrs. Bayliss was losing her ability to speak and even sought speech therapy treatment, which was unsuccessful.

39. On or about January 6, 2011, Plaintiff, was still in pain and having trouble moving around, went to Dr. Durrani and received a steroid injection.

40. In June 2011, Plaintiff's family physician, Dr. Mital, sent her to Doverwood Village for additional rehab.

41. On or about June 21, 2011, Mrs. Bayliss saw Dr. Durrani, after waiting for two hours. At this time, Plaintiff was still in extreme pain.

42. On or about June 30, 2011, Dr. Mital ordered another MRI of Mrs. Bayliss's back.

43. On or about July 5, 2011, Plaintiff returned to Doverwood Village for additional rehab.

44. Over the next several months, Plaintiff continued a cycle of hospital visits and stints in rehab. Throughout this time, Mrs. Bayliss lost her ability to speak, could not eat without choking. She lost an extreme amount of weight, going from 125lbs to 90lbs. She had to be lifted from a bed or chair to be wheeled around.

45. In less than a year, Mrs. Bayliss went from an independent, active person, to being unable to speak, requiring assistance for daily life activities.

46. In November 2011, Mrs. Bayliss was admitted to Heritage Springs, where she continued to be in extreme pain unable to eat, walk, or talk. She was able to write notes and point at thing. Her pain was in her neck and all down her back.

47. On or about December 26, 2011, Plaintiff was admitted to West Chester Hospital for dehydration. When the family arrived at the hospital, they learned that she had fallen into a coma.
48. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
49. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.
50. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiffs have suffered harm.
51. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

KEVIN & HILLARY HARTNESS

52. At all times relevant, Plaintiffs, Kevin and Hillary Hartness, ("Plaintiffs" or "Plaintiff") were married and residents of and domiciled in the State of Ohio.
53. Plaintiff, Mr. Hartness, sought treatment with Dr. Durrani in early 2009 for lower back pain related to an automobile accident in 2007.
54. Dr. Durrani recommended surgery on Plaintiff to relieve pain.
55. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

56. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
57. On or about September 18, 2010, Dr. Durrani performed surgery on Plaintiff at West Chester Hospital. Specifically, Dr. Durrani performed a Direct Lateral Lumbar Interbody Fusion L3-L5 with instrumentation.
58. The use of BMP-2 increases a person's chance of cancer by 3.5%
59. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
60. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
61. Plaintiff's back pain increased immediately following surgery. Plaintiff continued to seek treatment with Dr. Durrani for this pain. Each visit Dr. Durrani would recommend another surgery.
62. On or about March 23, 2011, Dr. Durrani performed surgery on Plaintiff's neck at West Chester Hospital. Specifically, Dr. Durrani performed an Anterior Cervical discectomy C6-C7 with Instrumentation.
63. Plaintiff's pain in his neck and back increased dramatically after the second surgery.
64. Plaintiff continued to follow up with Dr. Durrani and inform him of this new and worsening pain.
65. Dr. Durrani continued to tell Plaintiff to give it time.
66. Plaintiff continues to live with constant discomfort and pain in his neck, back, and arms since the surgeries.

67. Plaintiff is no longer able to drive, has a loss of intimacy with his fiancé, and experiences migraines, since the surgery with Dr. Durrani.
68. Plaintiff relies on his fiancé to drive him and helps with most of the household chores.
69. Plaintiff is not able to activities that he once enjoyed, like hunting and fishing.
70. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
71. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.
72. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiffs have suffered harm.
73. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

CAROLYN & WILLIAM HURSONG

74. At all times relevant, Carolyn and William Hursong, were married and were residents of and domiciled in the State of Ohio.
75. Plaintiff was referred to seek treatment with Dr. Durrani in 2010 for neck pain that radiated down bilaterally into her arms. She also was experiencing numbness with this pain.
76. Dr. Durrani recommended surgery on the first office visit.
77. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through

October 5, 2010.

78. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
79. On or around October 1, 2010, Dr. Durrani performed a spinal fusion and anterior cervical discectomy on Plaintiff at West Chester Hospital.
80. After the surgery, Plaintiff's pain progressively got worse. She continued to follow up with Dr. Durrani and complain of this pain.
81. Dr. Durrani informed Plaintiff the screws from the first surgery were out of place and he needed to do a revision surgery.
82. On or about July 11, 2011, Dr. Durrani performed a revision surgery of Plaintiff's spine at West Chester Hospital.
83. Plaintiff continued to follow up with Dr. Durrani and her pain levels stayed extremely high. She lost flexibility in her neck following the second surgery.
84. Additionally, Plaintiff has blackouts, if she turns her neck to a certain degree. This did not happen before the surgeries.
85. Plaintiff continues to live with pain, discomfort, and numbness. Her quality of life has diminished as a result of the surgeries performed by Dr. Durrani.
86. Upon information and belief, the surgeries upon Plaintiff by Dr. Durrani were medically unnecessary.
87. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff.

Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

88. As a result of the negligence of the Defendants named herein, Plaintiffs have suffered damages including medical expenses, pain and suffering and loss of enjoyment of life.

89. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

CHRIS MCCAUGHEY AS EXECUTOR OF THE ESTATE OF SARAH JUERGENS

90. At all times relevant, Sarah Juergens, was a resident of and domiciled in the State of Ohio.

91. Plaintiff first began treatment with Dr. Durrani in 2009.

92. Shortly after beginning her first treatment with Dr. Durrani, he informed her that she needed to undergo surgery. However, Dr. Durrani also informed her that he could not perform this surgery because it was "too dangerous and tedious an operation."

93. Soon after, Dr. Durrani persuaded Plaintiff that he could perform a "minimally invasive" technique that would allow the proposed surgery, and that Plaintiff would experience immediate pain relief following this "minimally invasive" surgery.

94. No conservative treatment options were discussed, recommended, or attempted prior to Dr. Durrani telling the Plaintiff that she needed surgery.

95. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

96. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

97. On September 12, 2010, Dr. Durrani performed an extensive lateral entry surgery on the Plaintiff at West Chester Hospital and implanting hardware into the Plaintiff's spine ["the first surgery"].
98. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this first surgery without Plaintiff's knowledge or consent, causing harm.
99. The use of BMP-2 increases a person's chance of cancer by 3.5%
100. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
101. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
102. Following this first surgery, Plaintiff began experiencing new, worse pain than she did prior to the surgery.
103. Since that time, this new pain has neither resolved nor subsided.
104. On or around October 27, 2010, Dr. Durrani performed a second extensive surgery to the Plaintiff's thoracic spine that required the installation of several pieces of hardware ["the second surgery"].
105. Upon information and belief, Dr. Durrani used BMP-2/Infuse or Puregen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.
106. At follow up appointments to these surgeries, Dr. Durrani assured Plaintiff that her pain and immobility would resolve and her condition would drastically improve.
107. In actuality Plaintiff's medical condition were extreme and worsening, but Dr. Durrani continued to falsely document that Plaintiff's condition was improving in his CAST notes.

108. On or around November 3, 2010, Defendants performed a corrective surgery to repair surgical mistakes and failed hardware from the first and second surgeries [“the third surgery”].

109. Thereafter, Plaintiff obtained no pain relief, and in fact, her condition continued to worsen.

110. Plaintiff, before her death, was permanently harmed, largely immobile, and in constant pain as the result of these failed and improper surgeries.

111. Plaintiff died on December 9, 2013.

112. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

113. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff do have surgery.

114. As a direct and proximate result of these surgeries and Dr. Durrani’s negligence, the Plaintiff has suffered harm.

115. Plaintiff did not become aware of Dr. Durrani’s use of Infuse/BMP-2 until legal counsel reviewed Plaintiff’s bills.

LINDA KALLMEYER-WARD

116. At all times, relevant Plaintiff was a resident of and domiciled in the State of Ohio.

117. In or around 2009, Ms. Ward began experiencing pain in her neck, low back, and left arm, along with numbness and tingling in her left arm.

118. Plaintiff's family physician referred her to Dr. Durrani.
119. In or around spring 2010, Ms. Ward first consulted with Dr. Durrani at CAST.
120. Upon information and belief, during her first visit with Dr. Durrani, Dr. Durrani told Ms. Ward that he could "fix" her problems and that surgery was necessary to resolve her pain.
121. Dr. Durrani diagnosed Ms. Ward with spinal stenosis and disc degeneration at L3-L4, anterolisthesis of L3 on L4, and disc herniation with spinal stenosis.
122. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.
123. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
124. On or about August 30, 2010, Dr. Durrani performed an anterior cervical discectomy fusion using autograft and allograft at C5-C6 and C6-C7, placed anterior cervical cages at C5-6 and C6-7, and placed anterior cervical instrumentation at C5-6 and C607, on Plaintiff at West Chester Hospital.
125. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label" and/or Puregen without Plaintiff's knowledge or consent, causing Plaintiff harm.
126. The use of BMP-2 increases a person's chance of cancer by 3.5%
127. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
128. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

129. In or around September 13, 2010, Plaintiff visited CAST for a follow up appointment.
130. A staff member of CAST noted that Plaintiff's wound looked great but that she was having difficulty swallowing and was experiencing pain in her shoulder blades.
131. On or about September 23, 2010, Ms. Ward visited Dr. Durrani at CAST for a pre-op visit regarding her upcoming second surgery.
132. Upon information and belief, during the September 23, 2010 visit, Dr. Durrani did not address Ms. Ward's current condition or status.
133. On or about October 4, 2010, Dr. Durrani performed a direct lateral lumbar fusion at L3-4 using autograft and allograft, placed a lateral interbody cage at L3-4, placed posterior spinal instrumentation at L3-4, and performed a posterior spinal fusion using autograft at L3-4 on Ms. Ward at West Chester Hospital.
134. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label" and/or PureGen without Ms. Ward's knowledge or consent, causing Ms. Ward harm.
135. On or about October 18, 2010, Ms. Ward attended her two-week post-op visit with Dr. Durrani at CAST.
136. It was noted at this visit that Ms. Ward was complaining of some minor low back pain, was walking daily, and that she was to begin physical therapy.
137. Plaintiff returned to work at CINTAS following her surgeries despite the fact that she experienced daily back pain as well as pain in her neck, arms, and legs.
138. In or around June 2011, Dr. Durrani recommended that Plaintiff receive lumbar epidural steroids to treat a large disc herniation at the L4-5 level.
139. In or around March 2012, Dr. Durrani recommended that Plaintiff undergo a third surgery.

140. In or around April 2012, Plaintiff was diagnosed with lung cancer and began visiting an oncologist.
141. Plaintiff had previously smoked but quit in 2007, five years before her lung cancer diagnosis.
142. BMP-2/Infuse is known to increase the risk of cancer.
143. Ms. Ward cancelled her scheduled third surgery with Dr. Durrani.
144. Ms. Ward continues to treat with her oncologist.
145. Ms. Ward now experiences daily pain in her neck and back, which limits her ability to perform everyday activities.
146. Plaintiff now has difficulty swallowing and experiences throat pain, which she did not experience prior to undergoing surgeries with Dr. Durrani.
147. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.
148. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.
149. As a direct and proximate result of Plaintiff's surgeries, Dr. Durrani's negligence, and the Defendant's negligence, Plaintiff has suffered harm.
150. Plaintiff did not become aware of Infuse/BMP-2 and/or Puregen until she contacted her undersigned counsel.

KATELYN KAUFFMAN

151. At all times relevant, Plaintiff was a resident of and domiciled in the State of Ohio.
152. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.
153. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
154. Plaintiff first met Dr. Durrani in September 2010 at his CAST offices in Evendale.
155. Plaintiff had been experiencing pain in her lower back and right leg.
156. Dr. Durrani reviewed Plaintiff's MRI previously taken in June or July of 2010 through Ohio Valley Orthopedics, and diagnosed Plaintiff with a herniated disc in her lower back.
157. Dr. Durrani recommended immediate surgery, and attempted to schedule such a procedure for the very next day; however, his schedule was already full at that time, and so a later date was needed.
158. Dr. Durrani advised the Plaintiff that if she did not have surgery within a short time, she would experience permanent nerve damage and become disabled.
159. Plaintiff was scheduled for a surgery to occur sometime within the two weeks following her appointment.
160. On September 22, 2010 Dr. Durrani and/or Dr. Shanti performed surgery on the Plaintiff that was supposed to consist of a right-side endoscopic discectomy from L5-S1 at West Chester Hospital.
161. Upon information and belief, Dr. Durrani and/or Dr. Shanti used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

162. The use of BMP-2 increases a person's chance of cancer by 3.5%
163. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
164. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
165. However, due to failure to dock the endoscopic ports onto the L5-S1 disc, this was converted to an open procedure.
166. Plaintiff did not learn of the change in her procedure until she awoke from surgery, after the surgery had already been performed.
167. Plaintiff was told that her procedure would require a small "keyhole" sized incision in her back; instead, she awoke with a four-inch incision in her back that required extensive recuperation far beyond the 2-3 weeks' recovery time she had previously been given.
168. Following the surgery, Plaintiff required the maximum usage of morphine that the hospital allowed.
169. After nearly seven weeks of recovery and physical therapy, Plaintiff finally felt up to returning to work.
170. However, as a result of the constant and severe pain that she now suffers, Plaintiff has been unable to find work in her chosen field and is struggling under the weight of the bills levied against her by Dr. Durrani, Dr. Shanti, CAST, and West Chester Hospital/UC Health.
171. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.

172. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.

173. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiff has suffered harm.

174. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiff's bills.

AMANDA KOCH

175. At all times relevant, Amanda Koch, was a resident and domiciled in the State of Ohio.

176. At the time, Plaintiff sought the advice of Dr. Durrani, she was experiencing intense pain and could barely walk.

177. On or around December 10, 2007, Dr. Durrani performed surgery on the Plaintiff at Children's Hospital. [the first surgery] She was only fourteen years old.

178. Upon information and belief, Dr. Durrani used Infuse/BMP-2 "off-label" in this first surgery without Plaintiff's knowledge or consent, causing harm.

179. The use of BMP-2 increases a person's chance of cancer by 3.5%

180. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

181. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.

182. After her first surgery, Plaintiff's pain became unbearable. Dr. Durrani recommended a second surgery be performed to correct this pain.
183. Before this second surgery could take place, Plaintiff would lose almost all feeling in her legs and lower extremities.
184. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.
185. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
186. On or around September 20, 2010, Dr. Durrani performed surgery on the Plaintiff at West Chester Hospital ["the second surgery"]. Plaintiff was seventeen at the time of this surgery.
187. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or PureGen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.
188. The use of BMP-2 increases a person's chance of cancer by 3.5%
189. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
190. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
191. About three days after her second surgery when Amanda Koch began to try to walk her legs began to "give out" causing her to fall. Amanda Koch was in constant pain after the surgery with Dr. Durrani.

192. Plaintiff informed Dr. Durrani of her pain and trouble walking. Dr. Durrani prescribed injections for Plaintiff, which did nothing to relieve her pain.
193. On or around August 2012, Dr. Durrani performed a revision surgery on the Plaintiff at West Chester Hospital ["the third surgery"].
194. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or PureGen "off-label" in this second surgery without Plaintiff's knowledge or consent, causing harm.
195. The use of BMP-2 increases a person's chance of cancer by 3.5%
196. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
197. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
198. Plaintiff is in constant pain every day and has extreme difficulty sleeping due to this pain.
199. Plaintiff is a mother of two children and due to the damage caused by Dr. Durrani she is unable to perform everyday activities.
200. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
201. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failure to disclose vital information, and improperly induced the Plaintiff to have surgery.

202. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiff has suffered harm.

203. Plaintiff did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiff's bills.

RUVIMBO NYEMBA

204. At all times relevant, Plaintiff was a resident and domiciled in the State of Ohio.

205. Plaintiff was referred to Dr. Durrani at Cincinnati Children's Hospital Medical Center by her elementary school after a routine school examination for scoliosis.

206. At the time of referral, Plaintiff was experiencing pain only occasionally; usually if she remained standing for long periods of time.

207. Dr. Durrani decided to keep a close eye on Plaintiff's "curve growth" until her physical development stabilized.

208. When Plaintiff turned 16 years of age, Dr. Durrani recommended that Plaintiff undergo a spinal fusion surgery to adjust the curvature of her spine.

209. Dr. Durrani assured the Plaintiff that she would be "back to normal" in three weeks.

210. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

211. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

212. On September 15, 2010, Dr. Durrani performed surgery on the Plaintiff consisting of a spinal fusion at West Chester Hospital.

213. After this surgery, the operative report was not dictated, by Dr. Durrani, for 47 days.

214. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.
215. The use of BMP-2 increases a person's chance of cancer by 3.5%
216. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
217. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased fear of Cancer.
218. After this surgery, Plaintiff received follow-up treatment from Dr. Durrani and CAST.
219. Plaintiff now suffers from extreme pain that is worse than any she experienced prior to the surgery. In addition, she has lost a fair measure of her flexibility.
220. Plaintiff continued to follow up with Dr. Durrani until August or September of 2012.
221. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
222. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failure to disclose vital information, and improperly induced the Plaintiff to have surgery.
223. As a direct and proximate result of this surgery and Dr. Durrani's negligence, the Plaintiffs have suffered harm.

RONALD ROWLEY

224. At all times relevant, Plaintiff, Ronald Rowley, ("Plaintiff") was a resident of and domiciled in the State of Ohio.
225. In early 2010, Plaintiff's primary care physician referred Plaintiff to Dr. Durrani and CAST in Blue Ash for low back and leg pain.
226. On March 25, 2010, at Plaintiff's initial visit with Dr. Durrani at CAST, Dr. Durrani stated he would "fix" Plaintiff and immediately recommended Plaintiff undergo surgery on his lumbar spine.
227. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges, until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.
228. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.
229. On August 25, 2010 at West Chester Hospital, Dr. Durrani operated on Plaintiff's lumbar spine. Specifically, Dr. Durrani performed a fusion and placed a lateral interbody cage at L4-L5.
230. During the August 25, 2010 surgery, Dr. Durrani used Infuse/BMP-2 "off-label" without Plaintiff's knowledge of consent, causing Plaintiff harm.
231. The use of BMP-2 increases a person's chance of cancer by 3.5%
232. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

233. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.
234. After surgery, Plaintiff treated with Dr. Durrani at CAST in Blue Ash, until June 2010.
235. After surgery with Dr. Durrani, Plaintiff continues to experience sever pain, which is much worse than the pain he experienced prior to undergoing surgery with Dr. Durrani.
236. Upon information and belief, the surgeries performed by Dr. Durrani were medically unnecessary and improperly performed.
237. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.
238. As a direct and proximate result of Plaintiff's surgeries, Dr. Durrani's negligence, and the Defendant's negligence, Plaintiff has suffered harm.
239. Plaintiff did not become aware of Infuse/BMP-2 and/or PureGen until he contacted her undersigned counsel.

BILLY SPIVY

240. At all times relevant, Plaintiff was a resident of and domiciled in the State of Ohio.
241. Plaintiff sought treatment with Dr. Durrani in January 2007 because of intermittent numbness in his right leg that would cause it to go to sleep.
242. Dr. Durrani recommended lumbar surgery on the first visit.
243. On February 9, 2007, Dr. Durrani performed lumbar fusion surgery at Christ Hospital.

244. Immediately following surgery, Plaintiff began experiencing back pain and could physically feel the hardware under his skin.
245. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.
246. The use of BMP-2 increases a person's chance of cancer by 3.5%
247. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.
248. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.
249. Plaintiff complained to Dr. Durrani about the new pain and Dr. Durrani informed him the only things that would relieve him of this would be a follow up surgery to get a disc off of a nerve in his back.
250. On March 27, 2009, Dr. Durrani performed a cervical fusion surgery on Plaintiff at Christ Hospital. Plaintiff stayed in the hospital approximately 7 days following this surgery because of complications with excessive bleeding.
251. Following this surgery, Plaintiff had an increase in back pain and began experiencing a new pain in his lower back and right leg.
252. Plaintiff continued to follow up with Dr. Durrani and complain of the pain, Dr. Durrani told him to give it a year to heal.
253. After continued pain and follow up treatment, Dr. Durrani recommended another surgery to help alleviate the pain.
254. On August 6, 2010, West Chester Hospital suspended Dr. Durrani's surgical privileges,

until Dr. Durrani completed surgical charts and the suspension was in effect at least through October 5, 2010.

255. Upon information and belief, Dr. Durrani, CAST, and West Chester Hospital/UC Health never informed Plaintiff that Dr. Durrani's privileges were suspended.

256. On September 17, 2010, Dr. Durrani performed a cervical fusion on Plaintiff on the back of his neck at West Chester Hospital.

257. Upon information and belief, Dr. Durrani used Infuse/BMP-2 or Puregen "off-label" in this surgery without Plaintiff's knowledge or consent, causing harm.

258. The use of BMP-2 increases a person's chance of cancer by 3.5%

259. Due to the unnecessary surgeries Dr. Durrani performed, Plaintiff has a 3.5% increased chance of cancer because of the use of BMP-2.

260. As a direct and proximate result of the use and implementation of Infuse/BMP-2 Plaintiff has incurred a 3.5% increase in the risk of Cancer. As a result, Plaintiff has an increased.

261. Upon information and belief, Dr. Durrani did not explain to Plaintiff that hardware would be implanted in his spine pre-operatively.

262. Plaintiff received a staph infection from this surgery and had major health complications due to this infection.

263. On February 28, 2011, Plaintiff has to undergo heart surgery and became unresponsive on the operating table. He was resuscitated.

264. The operating doctor informed Plaintiff his surgical history had affected his heart.

265. Since Plaintiff has difficulty moving around, since Dr. Durrani performed surgery on him, he has had to move to an assisted living nursing facility.

266. Plaintiff now requires assistance to get dressed, bathing, shaving, preparing meals, mailing bills, cleaning, and with the grocery shopping.
267. He has difficulty walking, sleeping and standing.
268. He has limited flexibility of his neck ever since the surgeries with Dr. Durrani.
269. Plaintiff is no longer able to drive, since the surgeries with Dr. Durrani.
270. Upon information and belief, the surgery performed by Dr. Durrani was medically unnecessary and improperly performed.
271. Upon information and belief, Dr. Durrani was performing surgeries while his surgical privileges were suspended. Dr. Durrani never informed the Plaintiff of the suspension and acted as if every surgery was an emergency, so that he could perform surgery on the Plaintiff. Dr. Durrani mislead, failed to disclose vital information, and improperly induced the Plaintiff to have surgery.
272. As a direct and proximate result of these surgeries and Dr. Durrani's negligence, the Plaintiffs have suffered harm.
273. Plaintiffs did not become aware of Dr. Durrani's use of Infuse/BMP-2 until legal counsel reviewed Plaintiffs' bills.

ADDITIONAL BACKGROUND INFORMATION:

274. Defendants fraudulently induced Plaintiff and her insurance company to pay for the surgery.
275. According to CFO Mike Jeffers, West Chester Hospital was in the business of making as much money as possible regardless of their non-profit status.
276. According to CFO Mike Jeffers, it would be against West Chester Hospital's interest to do something that would limit their earning potential or stop making money.

277. According to CFO Mike Jeffers, Dr. Durrani was the highest monthly revenue generator at West Chester Hospital.
278. The Board of Directors of UC Health, according to CFO Mike Jeffers, were aware of the financial growth of the hospital and of the orthopaedic and spine department and in particular the significant financial revenue generated from Dr. Durrani's surgeries.
279. According to CFO, Mike Jeffers, West Chester Hospital billed more for BMP-2 and PureGen than what they purchased the items for.
280. According to CFO, Mike Jeffers, West Chester Hospital tracked the occupancy of their 162 beds by floor.
281. According to CFO, Mike Jeffers, at the end of each month there was a reporting packet that was requested from all the finance directors, and it would be sent to the corporate controller Charity Fannin regarding the monthly finances.
282. According to CFO, Mike Jeffers, the information was tracked by each individual patient in the hospital.
283. According to Annual Reports put together by Jeff Hinds and financial statements of West Chester/UC Health from 2009 through 2013, the Defendants violated R.C. 1702(54), by knowingly placing false information in numerous documents governed by R.C. 1702(54) including over \$4 million dollars falsely claimed as income for Medicaid/Medicare fraud and other false statements in their prospective, reports, financial statements, minutes, records and accounts.
284. West Chester/UC Health made more money from surgical patients than medical patients. Dr. Durrani was a spine surgeon.

285. West Chester/UC Health made more money from more surgical procedures and more diagnostic tests and therapeutic procedures of any kind. Dr. Durrani ordered significant unnecessary diagnostic tests and procedures for his patients and the Defendants knew this fact.
286. Complex cases made West Chester/UC Health more money than simple ones. Dr. Durrani had complex cases.
287. There have been serious consequences since orthopedic device companies began sending sales representatives to the operating room of hospitals as they did and do to West Chester/UC Health.
288. The sales representatives assist the back table with the instruments, technique and managed inventory. This has allowed the hospitals to allow their staff to not know specifics about cases and orthopedic systems. This has also allowed the hospitals to avoid the cost of training their staffs for what the sales representatives do. This all applies to West Chester/UC Health
289. The sales representative adds approximately 40% to the cost of the implant and increases implant usage to 30% at West Chester/UC Health.
290. The Dr. Durrani saga at West Chester is Exhibit A of the medical complex run amok for profit and greed over patient care.
291. West Chester/UC Health failed to report a single incident of any kind involving Dr. Durrani to the National Practitioner Data Bank and any other reporting agency including the Ohio Medical Board despite there being countless required reports.
292. According to HRSA Data, 42% of hospitals have never made a single report to NPDB.

293. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.
294. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.
295. From January 2009 through May 2013, with respect to Dr. Durrani, Defendants failed to follow their Medical Staff Code of Conduct which they approved as witnessed by Ed Crane, President of the Medical Staff and Paula Hawk.
296. Unknown Defendants include all Members of the Executive Committee, Credentialing Committee and Peer Review from 2009 through 2013.
297. Article I of the MEC bylaws gives the MEC "oversight," of quality of care and patient safety for West Chester.
298. Article 3.1.1 sets forth who the officers are including President, Director of Surgery, Director of Medicine and Chair of Credentials Committee.
299. Article 3.3.1 provides the duties of each department director and Article 4.4 provides the functions of the department.
300. Defendants have refused to produce through discovery the members of West Chester's Medical Executive Committee, Credentialing Committee and Peer Review Committee from 2009 through 2013.
301. According to Barbara Butz, she prepared the application for credentials to be reviewed by the department directors, the credentialing committee, the MEC and the Board.
302. According to Grant Wenzel, there was a marketing campaign that "spoke of our capabilities" in spine surgery.

303. West Chester/UC Health and the Defendants allowed Dr. Durrani from at least August 1, 2010 to October 5, 2010 to perform surgeries at West Chester while suspended. Over 30 patients had surgeries during this time period. This intentional egregious conduct is appalling and represents fraud in the concealment. None of these 30 plus patients would have allowed Dr. Durrani to perform their surgery had they known Dr. Durrani was suspended.

304. West Chester/UC Health and Defendants bragged about and still brag about their spine surgery capabilities.

305. West Chester/UC Health failed to comply with their Medical Staff Bylaws which include:

- a) Bylaws
- b) Credentialing Plan
- c) Rules and Regulations

306. The list of negligent acts, intentional acts and fraudulent acts by Dr. Durrani known to the hospital management, administration and board members including these Defendants include:

- 1) Dr. Durrani was the #1 money making doctor for West Chester.
- 2) West Chester planned to lease Dr. Durrani the fourth floor of the hospital for CAST physical therapy.
- 3) According to Paula Hawk, West Chester and Dr. Durrani were "partners in crime."
- 4) West Chester allowed three days of blocked surgery time and allowed more than one surgery at a time.
- 5) West Chester ignored their Medical Executive Committee bylaws when it came to credentialing and retaining Dr. Durrani.

- 6) West Chester West Chester/UC Health knew BMP-2 was being used improperly by Dr. Durrani including in minors, non-approved locations in the spine and in patients with cancer risks.
- 7) West Chester/UC Health knew Dr. Durrani was doing extensive multiple surgeries on patients.
- 8) West Chester/UC Health knew of Dr. Durrani's issues at other issues at hospitals before his application of privileges at West Chester.
- 9) West Chester/UC Health knew about the "Shanti Shuffle" which is an expression to describe Dr. Shanti, Dr. Durrani's employee spine surgeon, performing spine surgeries for Dr. Durrani without the consent of the patient.
- 10) West Chester/UC Health knew about "emergency" add on issue where Dr. Durrani would claim a surgery was an emergency to add it on to an existing schedule.
- 11) West Chester/UC Health knew PureGen was being used improperly by Dr. Durrani including that was never approved for human use and they bought it from Dr. Durrani.
- 12) West Chester/UC Health knew Dr. Durrani was the biggest revenue generator.
- 13) West Chester/UC Health knew Dr. Durrani would perform multiple surgeries at the same time in the OR.
- 14) West Chester/UC Health knew Dr. Durrani was not dictating OR reports or dictating them extremely late, often times up to six months.
- 15) West Chester/UC Health knew Dr. Durrani's patients had extended anesthesia waiting for surgery.
- 16) West Chester/UC Health marketed themselves as a world leader in spine surgery.
- 17) West Chester/UC Health knew Dr. Durrani was "over-utilizing."
- 18) The officers and administrators in depositions have admitted West Chester/UC Health knew of the issues involving Dr. Durrani.

- 19) West Chester/UC Health knew Dr. Durrani was not obtaining proper informed consents from his patients.
- 20) West Chester/UC Health knew Dr. Durrani dictated discharge summaries late and sometimes not at all.
- 21) West Chester/UC Health knew they were not following their bylaws, rules and policies in their supervision of Dr. Durrani.
- 22) West Chester/UC Health knew Dr. Durrani was abusive to staff.
- 23) West Chester/UC Health knew Dr. Durrani was "sloppy" in surgery.
- 24) West Chester/UC Health knew staff and medical staff would lie regarding Dr. Durrani issues.
- 25) West Chester/UC Health forced silence upon staff and medical staff.
- 26) West Chester/UC Health tracked BMP-2 use by Dr. Durrani to calculate their profits from its use.
- 27) West Chester/UC Health knew Dr. Durrani performed surgeries too late into night to the detriment of patient safety.
- 28) West Chester/UC Health knew Dr. Durrani's use of improper hardware in spinal surgeries.
- 29) West Chester/UC Health knew Dr. Durrani sometimes marketed himself as a neurosurgeon to patients.
- 30) West Chester/UC Health knew Dr. Durrani performed procedures beyond his scope of practice and training.
- 31) West Chester/UC Health knew Dr. Durrani performed surgeries with inadequate training.
- 32) West Chester/UC Health knew Dr. Durrani used "cut and paste" in his OR reports.

- 33) West Chester/UC Health knew Dr. Durrani engaged in improper financial relationships with orthopaedic product vendors.
- 34) West Chester/UC Health knew Dr. Durrani had the lack of attention to detail as required of a spinal surgeon.
- 35) West Chester/UC Health knew multiple Dr. Durrani patients suffered from improper VATS procedures, resulting in various reactive airway diseases postoperatively.
- 36) West Chester/UC Health knew they did not do proper credentialing procedures of Dr. Durrani prior to privileging him as a surgeon.
- 37) West Chester/UC Health knew Elizabeth Garrett (physician's assistant) was present and active in the OR as an assistant surgeon without the proper approval.
- 38) West Chester/UC Health allowed and promoted Dr. Durrani to give seminars knowing he misrepresented his status at Children's Hospital and University Hospital.
- 39) West Chester/UC Health knew Dr. Durrani had an improper personal relationship with Elizabeth Garrett.
- 40) West Chester/UC Health knew that the required tracking paperwork of BMP-2 and PureGen was not routinely completed in the OR.
- 41) West Chester/UC Health knew Dr. Durrani's patients were having anesthesia related complications intraoperatively and postoperatively, and did not disclose it to patients.
- 42) West Chester/UC Health knew Dr. Durrani failed to disclose to patients and family medical problems encountered during surgery.
- 43) West Chester/UC Health knew Dr. Durrani was creating health care billing fraud and they too committed billing fraud.
- 44) West Chester/UC Health knew Dr. Durrani handpicked patients with optimal health insurance for unnecessary surgeries to profit himself and the hospital.

45) West Chester/UC Health knew Dr. Durrani often did not contact his patient's primary care practitioner for in-patient hospital follow up appointments, and instead picked West Chester staff to cover maximize profit, and not have to disclose his wrongdoings.

307. The hospital's management administration and board members, including the Defendants, knew of the improper use of BMP-2 and PureGen by not only Dr. Durrani, but other surgeons. This Complaint contains detailed sections pertaining to these two substances.

308. There were over 185 BMP-2 victims and over 84 PureGen victims at West Chester/UC Health, all Dr. Durrani patients. There are hundreds and even probably over a thousand or more past patients of West Chester/UC Health who have no idea they have BMP-2 or PureGen in their spines and they are encountering health issues they have no idea could be caused by BMP-2 or PureGen. Two separate class actions on this issue will be filed simultaneous with this lawsuit.

309. The Annual Reports of UC Health reflect the bragging by the management, administration and board, including Defendants, of West Chester's financial performance and spine awards with full knowledge of the false information contained in them including over \$4 million in fraudulent Medicaid and Medicare billings. The one for the Fiscal year ended June 30, 2013 is the last one applicable to Dr. Durrani, his last year at West Chester.

MORE SPECIFIC ALLEGATIONS BASED UPON DISCOVERY AND DEPOSITION

TESTIMONY

310. This information is to demonstrate the overall negligence and inappropriate actions of Dr. Durrani and the hospitals he worked with and/or for and/or in an individual capacity.

311. Krissy Probst was Dr. Durrani's professional and personal assistant handling professional, academic, travel, surgery scheduling, his journals, his Boards, his credentialing, his personal affairs and his bills.

312. Krissy Probst worked as Dr. Durrani's assistant for three years at Children's Hospital from 2006, 2007, and 2008.

313. Krissy Probst reported Dr. Durrani to Sandy Singleton, the Business Director at Children's for his having an affair with Jamie Moor, his physician assistant.

314. Krissy Probst resigned in 2008 from Dr. Durrani and remained working for three other surgeons in the Orthopedic Department.

315. Krissy Probst worked in the Orthopedic Department for eleven years from 2002-2013. She retired in May, 2013.

316. Krissy Probst confirmed Dr. Durrani claims being a Prince, when he is not.

317. According to Krissy Probst, Dr. Crawford, an icon in pediatric orthopedics treated Dr. Durrani "like a son."

318. According to Krissy Probst, Dr. Crawford, Chief of Orthopedics at Children's unconditionally supported Dr. Durrani no matter the issues and problems Dr. Durrani faced.

319. Dr. Durrani's patient care at Children's Hospital dropped off considerably after Jamie Moor became his physician assistant and they began their affair.

320. Dr. Durrani was the only orthopedic spine surgeon at Children's who would perform a dangerous high volume of surgeries.

321. At Children's, Dr. Durrani would begin a surgery, leave and have fellows and residents complete a surgery or do the full surgery while he was in his office with Jamie Moor, his physician assistant for four or five hours.

322. Children's Board and administration knew about Dr. Durrani doing too many surgeries and not properly doing the surgeries. They did nothing.

323. Dr. Durrani argued to Children's administration when they complained to him that he made them money so Children's tolerated him and allowed him to do what he wanted.

324. Dr. Durrani, when told by Children's that Jamie Moor had to leave, told Children's that he would leave too.

325. Dr. Agabagi would do one spine patient a day at Children's because it takes normally eight hours for a full fusion.

326. Dr. Durrani would schedule two to three spine surgeries a day at Children's.

327. Dr. Durrani would repeatedly have the Business Director, Sandy Singleton, or OR Director allow him to add surgeries claiming they were emergencies when they were not.

328. Dr. Durrani would leave a spine surgery patient for four or five hours in the surgery suite under the care of fellows or residents, unsupervised and sit in his office and check on the surgery as he pleased.

329. Dr. Peter Stern did not like Dr. Durrani while Dr. Durrani was at Children's because he knew all about his patient safety risk issues. Yet, Dr. Stern supported, aided and abetted Dr. Durrani's arrival at West Chester. It defies comprehension, but was for one of the world's oldest motives—greed of money.

330. There is also a Dr. Peter Sturm, an orthopedic at Children's who also had no use for Dr. Durrani.

331. Dr. Durrani chose his own codes for Children's billing which he manipulated with the full knowledge of Children's Board and management.

332. Dr. Durrani was dating and living with Beth Garrett, a nursing school drop-out, with the full knowledge of his wife Shazia.
333. Dr. Durrani was close with David Rattigan until David Rattigan pursued Jamie Moor and Dr. Durrani would not allow David Rattigan in the OR at Children's for a long time.
334. Dr. Durrani, while claiming to have riches, does not. Dr. Durrani's wife's family paid for Dr. Durrani's education and it is her family with the significant wealth.
335. Medtronics paid for Dr. Durrani's trips and paid him \$10,000 fees for speaking or simply showing up at a spine conference.
336. Krissy Probst's business director told her to save all Dr. Durrani related documents and information and she did.
337. While doing research at Children's, Dr. Durrani would misstate facts regarding his research. Children's knew he did this.
338. Dr. Durrani ended on such bad terms with Children's Hospital he was not allowed on the premises after his departure in December 2008, yet he performed a spine surgery there in February 2009.
339. Eric J. Wall, MD was the Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.
340. Sandy Singleton, MBA was the Senior Business Director of Surgical Services Division of Pediatric Orthopedic Surgery when Dr. Durrani left Children's.
341. On information and belief, Dr. Durrani used his relationships with Children's officials to purge his Children's file of all patient safety and legal issues which had occurred as part of his departure "deal" which Defendants hide with privilege.

INFUSE/BMP-2

I. BACKGROUND INFORMATION

342. The Deters Law Firm, P.S.C., represents approximately 500 Plaintiffs in medical malpractice actions against a former Northern Kentucky/Cincinnati-area spine surgeon named Abubakar Atiq Dr. Durrani (Dr. Durrani), his company, Center for Advanced Spine Technologies, Inc. (CAST), and several area hospitals including, but not limited to, West Chester Hospital (WCH), University of Cincinnati Health (UC Health), Cincinnati Children's Hospital Medical Center (CCHMC), Christ Hospital, Deaconess Hospital, Good Samaritan Hospital and Journey Lite of Cincinnati, LLC (Journey Lite) (collectively Hospitals).

343. Dr. Durrani performed unnecessary, fraudulent, dangerous, and ultimately damaging surgeries on these Plaintiffs while working for and with these Hospitals.

344. The scheme and artifice to defraud that Dr. Durrani devised, executed, and attempted to execute while working for and with the Hospitals included the following patterns and practices:

- a. Dr. Durrani persuaded the patient that surgery was the only option, when in fact the patient did not need surgery.
- b. Dr. Durrani told the patient that the medical situation was urgent and required immediate surgery. He also falsely told the patient that he/she was at risk of grave injuries without the surgery.
- c. Dr. Durrani often told his cervical spine patients that they risked paralysis or that his/her head would fall off if he/she was involved in a car accident, ostensibly because there was almost nothing attaching the head to the patient's body.
- d. Dr. Durrani often ordered imaging studies such as x-rays, CT scans, or MRIs for patients but either did not read or ignored the resulting radiology reports.

- e. Dr. Durrani often provided his own exaggerated and dire reading of the patient's imaging study that was either inconsistent with or was plainly contradicted by the radiologist's report. At times, Dr. Durrani provided a false reading of the imaging.
- f. Dr. Durrani often dictated that he had performed certain physical examinations and procedures on patients that he did not actually perform.
- g. Dr. Durrani often ordered a pain injection for a level of the spine that was inconsistent with the pain stated by the patient or with that indicated by the imaging. Dr. Durrani also scheduled patients for surgeries without learning of or waiting for the results of certain pain injections or related therapies.
- h. Dr. Durrani often dictated his operative reports or other patient records months after the actual treatment had occurred.
- i. Dr. Durrani's operative reports and treatment records contained false statements about the patient's diagnosis, the procedure performed, and the instrumentation used in the procedure.
- j. When a patient experienced complications resulting from the surgery, Dr. Durrani at times failed to inform the patient of, or misrepresented the nature of, the complications.
- k. All of the above-mentioned actions were done with the knowledge, cooperation, or intentional ignorance of the Hospitals because Dr. Durrani was one of the biggest moneymakers for the Hospitals.

345. In addition to the civil medical malpractice actions against Dr. Durrani, on August 7, 2013, he was indicted by the Federal Government for performing unnecessary surgeries and for defrauding the Medicare and Medicaid programs. Specifically, the ten-count complaint charged Dr. Durrani with health care fraud, in violation of 18 U.S.C. § 1347, and making false statements in health care matters, in violation of 18 U.S.C. § 1035. There was a subsequent superseding indictment adding over 30 counts.

346. Following these criminal indictments, in December of 2013 and prior to the first Plaintiff's trial in these actions, Dr. Durrani fled the United States and returned to Pakistan. He has not returned to the United States to face allegations of either criminal or civil liability.
347. Among Dr. Durrani's and the Hospitals' professional failings was the use of a synthetic bone-morphogenetic protein called BMP-2, which was marketed under the trade name "Infuse." Dr. Durrani used BMP-2/Infuse in ways that were either not approved by the federal Food and Drug Administration (FDA) or that were specifically contraindicated as noted on the FDA-approved product labeling. The Defendants had full knowledge of this fact.
348. BMP-2/Infuse was, at the time of the surgeries in question, and currently still is manufactured by a company called Medtronic, Inc. (Medtronic).
349. Dr. Durrani predominantly used BMP-2/Infuse on patients at WCH, which is owned by UC Health.
350. It is Plaintiffs' position that this non-FDA-approved use of BMP-2/Infuse was not only negligent, and fraudulent, but criminal based upon the manner in which it was allowed to be used by Dr. Durrani at West Chester, all with the knowledge and full support of the Defendants.

II. THE PLAYERS REGARDING BMP-2

351. Dr. Durrani is a citizen of the Republic of Pakistan and was a permanent resident of the United States who, from approximately 2005 to 2013, worked as a spine surgeon in and around Cincinnati, Ohio, until he fled the United States to escape civil liability and criminal prosecution.

352. Medtronic is an Irish corporation, with its principal executive office located in Dublin, Ireland, and its operational headquarters located in Minneapolis, Minnesota. Medtronic is the world's third largest medical device company and manufactures and markets BMP-2/Infuse. Medtronic sales representatives were also present during the experimental surgeries performed on Plaintiffs, who are clients of the Deters Law Firm.

353. CAST was a corporation organized under the laws of Ohio and had business and medical offices in Florence, Kentucky and Evendale, Ohio. CAST was owned, in whole or in part, by Dr. Durrani.

354. Bahler Medical, Inc. is a manufacturer of medical implants and is a corporation located in the state of Ohio.

355. David Rattigan is an Ohio resident and was and is a sales representative for Medtronic.

Further, he is affiliated with Bahler Medical, Inc., was involved in many of the transactions involving BMP-2, and was present for the experimental surgeries in which BMP-2 was used.

356. West Chester Hospital, LLC is a corporation organized under the laws of Ohio. It provides medical facilities and billing support to physicians, including Dr. Durrani, in the state of Ohio. WCH is owned by UC Health.

357. UC Health is a private, non-profit corporation organized under the laws of Ohio. It provides medical facilities, management, administrative, ancillary, and billing support to physicians, and it owns WCH.

358. CCHMC is a medical facility in Ohio where Dr. Durrani was an employee until approximately 2008.

III. WHAT IS BMP-2/INFUSE?

359. The full name of BMP-2 is “Recombinant Human Morphogenetic Protein-2” (also called rhBMP-2). The following definitions apply:

- a. Recombinant – Artificially created in a lab;
- b. Morphogenetic – Evolutionary development of an organism;
- c. Protein – Essential for growth and repair of tissue.

360. Recombinant human protein (rhBMP-2) is currently available for orthopedic usage in the United States.

361. Medtronic manufactured, marketed, sold, and distributed BMP-2 under the trade name “Infuse.”

362. BMP-2 has been shown to stimulate the production of bone.

363. Implantation of BMP-2 in a collagen sponge induces new bone formation and can be used for the treatment of bony defects, delayed union, and non-union.

BMP-2 AS A BIOLOGIC

364. BMP-2 is not a device, but instead it is a biologic. *See* July 2009 American Medical Association Article and 2011 Stanford School of Medicine Article.

365. According to the FDA, “[a] ‘biological product’ means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public Health Service Act Sec. 351(i)1.” Available <http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm>.

366. BMP-2 is a Bone-Morphogenetic Protein that is used to promote bone creation and remodeling and falls under the definition of a biologic. *See* AMA article (“bone forming

properties”) and Stanford Article. BMP-2 differs from a medical device in that once implanted, it can only be removed days after surgery. If a patient had a complication due to BMP-2 and did not discover this complication until year after surgery, the patient could not have BMP-2 removed to reduce the complication because BMP-2 is so integrated into the patient’s bone.

367. A patient has a right to determine what happens to his or her body and the preservation of that right requires that the patient be informed when a bone growth product, that causes irreversible harm, is placed in his or her body.

WHEN IS IT USED?

368. Recombinant human BMPs are used in orthopedic applications such as spinal fusions, non-unions, and oral surgery.
369. The bone graft contains two parts. The first is a solution of human bone growth protein or morphogenetic protein-2. This protein is found in the human body in small dosages and is important for the healing and formation of bones. The protein is genetically engineered to be utilized in the Infuse Bone Graft product, and it is employed for the stimulation of formation and growth in bones.
370. The second part of the bone graft is an absorbable collagen sponge.
371. Both components of the Infuse Bone Graft structure are used to fill the LT-Cage Lumbar Tapered Fusion Device. This chamber is intended to restore the deteriorated disc space to its original height.
372. FDA-approved use for the Infuse Bone Graft product is only for lower back surgery using an anterior lumbar interbody fusion (ALIF), a technique where the operation on the spine is conducted through the abdomen.

373. In addition, the Infuse Bone Graft product must be used in conjunction with Medtronic's LT-Cage. Use of BMP-2 without the LT-Cage is considered an "off-label" use.

CONTRAINDICATIONS OF USE

374. The FDA specifically warns against the use of Infuse in the cervical spine, citing reports of "life-threatening complications."

375. Any use of Infuse other than in lumbar spine surgeries with the LT-Cage is considered "off-label" use

376. Infuse should never be used on the skeletally immature patient, i.e., in patients less than 18 years of age or those with no radiographic evidence of epiphyseal closure.

377. Infuse should never be used in the vicinity of a resected or extant tumor.

378. Infuse should never be used in those patients known to have active infection at the surgical site.

RISKS ASSOCIATED WITH OFF-LABEL USE

379. When used in an off-label manner, patients may experience problems with pregnancy, including but not limited to: complications in fetal development; allergic reactions to titanium, bovine type I collagen, or bone morphogenetic protein-2; infection; the creation or intensification of tumors; liver or kidney disease; lupus or human immunodeficiency virus (HIV/AIDS); problems with radiation, chemotherapy, or steroids if a patient is malignant; paralysis; bowel and/or bladder dysfunctions; sexual disorders, including sterilization and incompetence; respiratory failure; excessive bleeding, and; death.

IV. THE REGULATORY PROCESS

380. The Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., established two separate approval processes for medical devices: Pre-Market Approval (PMA) and Pre-Market Notification.¹

381. The FDA's PMA process is lengthy and involves extensive investigation by the FDA.

The PMA application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require PMA applicants to submit copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(10). The FDA approves a PMA application only after extensive review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.²

382. In contrast, the FDA's Pre-Market Notification process is more abbreviated and involves less FDA oversight. This process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. Pre-Market Notification applicants must also submit their proposed labeling. 21 C.F.R. § 807.87. If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDA in 1976, the applicant is free to market the device.

¹ *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

² *Fender v. Medtronic*, 887 F.Supp. 1326 fn 1 (E.D. Cal.1995).

383. BMP-2 received PMA (PMA number P000058) for the Infuse/BMP-2 Lumbar Tapered Fusion Device, which PMA provided for limited use with specific requirements for its use on individuals. See Medtronic Package Insert.

SCOPE OF THE PMA AND PRODUCT LABELING

384. The PMA for BMP-2 provided that the product may only be used in patients with the following characteristics:

- d. Skeletally mature patient, AND
- e. At levels L2-S1, AND
- f. Confirmed degenerative disc disease (DDD), AND
- g. Using only an open anterior or anterior laparoscopic approach, AND³
- h. Six months of non-operative treatment prior to treatment with the device, AND
- i. In combination with the metallic LT-CAGE.⁴

See Medtronic Package Insert, "INDICATIONS."

385. According to Medtronic's package insert for BMP-2/Infuse as well as other industry literature, the following risks are associated with the use of BMP-2/Infuse:

- A. Male Sterility
- B. Cancer
- C. Increased progression of cancer
- D. Suffocation of the cervical region
- E. Bone fracture
- F. Bowel/bladder problems

³ The anterior interbody fusion approach was developed because the risk of non-union (pseudarthrosis) is significantly higher in posterior approaches. The biggest risk factor for fusion surgery is non-union.

⁴ Instrumented fusions involve hardware and are more stable fusions with a shorter recovery time than non-instrumented fusions.

- G. Loss of spinal mobility or function
- H. Change in mental status
- I. Damage to blood vessels and cardiovascular system compromise
- J. Excessive bone mass blocking the ability to treat pain
- K. Damage to internal organs and connective tissue
- L. Death
- M. Respiratory problems
- N. Disassembly and migration of components
- O. Dural tears
- P. Ectopic and exuberant bone formation
- Q. Fetal development complications (birth defects)
- R. Foreign body (allergic) reaction
- S. Gastrointestinal complications
- T. Incisional complications
- U. Infection
- V. Insufflation complications
- W. Neurological system compromise
- X. Non-union
- Y. Delayed union
- Z. Mal-union
- AA. Change in curvature of spine
- BB. Retrograde ejaculation
- CC. Scars
- DD. Tissue and nerve damage
- EE. Itching

- FF. Pain
- GG. Hematoma
- HH. Anaphylactic reaction
- II. Elevated erythrocyte sedimentation rate

386. Injury Percentages:

- j. Ectopic Bone Growth-63%
- k. Inflammatory Neuritis-15%
- l. Osteolysis/Subsidence-13%
- m. Acute Swelling-7%
- n. Retrograde Ejaculation-2%
- o. 85% of time, BMP-2 implanted in off-label use

387. Not a single one of these risks in the last two paragraphs were ever explained to a single patient at Children's Hospital by Dr. Durrani.

388. BMP-2 was NOT approved by the FDA for use in the cervical and thoracic spine and BMP-2 was NOT safe or approved for use in children less than 21 years of age. These uses are considered "off-label."

"OFF-LABEL" USE

389. A use of a device is considered "off-label" if it is not approved under the Pre-Market Approval process OR cleared for such use pursuant to 21 U.S.C. § 360c(f) (also known as "the 510k premarket notification process").

390. Infuse can be implanted in an off-label manner in three ways:

- p. Approach/position: Any approach other than an anterior approach;
- q. Product: Failure to use LT-Cage (or any cage); mixing rhBMP-2 with other grafting products like Allograft or Autograft;
- r. Discs: Use on multiple levels or on a level outside of L2-S1.

391. Dr. Durrani and the Hospitals in which he performed surgeries repeatedly used BMP-2 in these non-FDA-approved manners.

THE NON-COMPLIANCE WITH THE REGULATORY PROCESS

392. The PMA 000058 “Conditions of Approval” specifies the following condition: “Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by the FDA ... [a] PMA supplement or alternate submission shall comply with applicable requirements under 21 C.F.R. 814.39[.]”

393. 21 C.F.R. 814.39 requires a PMA supplement pursuant to subsection (a)(1) for new indications of use of the device and pursuant to subsection (a)(6) for changes in components.

394. The PMA 000058 “Conditions of Approval” notes the post-marketing reporting requirement imposed by 21 C.F.R. 814.84, particularly “Identification of changes described in 21 C.F.R. 814.39(a).” Medtronic did not comply with this requirement relating to the intended uses and componentry.

395. The FDA can impose post-approval requirements in the PMA pursuant to 21 C.F.R. 814.82, and this fact results in the device being characterized as “restricted” pursuant to 21 U.S.C. § 360j(e) for purposes of 21 U.S.C. § 352(q). Section 352(q) states that any restricted device that is distributed or offered for sale with false or misleading advertising is “misbranded.”

396. “Indications for use” is a necessary part of the PMA application and the “Indications for use” are required to be limited by the application. Any different use is inconsistent with the PMA.

397. A device that fails to meet the requirements of the PMA or 21 C.F.R. 814 is “adulterated” as defined by 21 U.S.C. § 351(f).

398. 21 C.F.R. 801.6 defines a misleading statement related to a DIFFERENT device contained in the label delivered with the device intended to be used will render the device to be used misbranded.

399. Medtronic did not apply for a PMA supplement, as required by the FDA generally and PMA 000058 specifically, for the off-label uses, nor did it provide warnings of the risks known about the off-label uses. All named Defendants in these cases knew about the occurrences of off-label use.

400. The PMA requires an application prior to marketing for new indicated uses by incorporating the federal requirements and explicitly reciting the text of 21 C.F.R. 814.39 and 814.84 and by specifically stating the range of indicated uses on the PMA.

V. MEDTRONIC

401. In or about 2001, Medtronic began preparing for the launch of two spinal fusion products, PYRAMID and INFUSE (BMP-2), which it projected would enjoy broad application with spinal surgeons and their patients on a nationwide basis.

402. Medtronic anticipated that both products would initially be limited in application.

403. Motivated by greed and a desire to gain competitive advantage in the marketplace, Medtronic began a course of conduct designed to broaden the application of both products by end-users. The course of conduct involved fraud, false statements, material misrepresentation, and deceit for the purpose of broadening the sales of these products beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

404. On or after July 2, 2002, Medtronic received notification that its Pre-Market Approval application for its BMP-2/Infuse bone graft products had been approved by the FDA.

However, such approval was limited to the application of the device from the L4 through S1 levels. Further, the approval mandated the conduct of post-approval studies to evaluate the long-term performance of the BMP-2 bone graft and to study the potential side effects and complications such as the promotion of tumors by the bone morphogenetic protein component of BMP-2. Other studies were conducted as well. See “Allegations against Medtronic in the Unsealed Mississippi False Claims Case.”

405. Medtronic engaged in a fraudulent course of conduct designed to maximize its revenues from BMP-2, regardless of whether it would eventually be allowed to remain on the market.

406. One of the physicians Medtronic co-opted into its fraudulent scheme was a Thomas A. Zdeblick, M.D. Dr. Zdeblick was an orthopedic surgeon whose invention, the LT-Cage, was the only approved device to act as the delivery vehicle for BMP-2 into the body.

407. Dr. Zdeblick enjoyed a position within the scientific community as a Key Opinion Leader, and he was both a practicing orthopedic surgeon and professor at the University of Wisconsin.

408. In one of Dr. Zdeblick’s first attempts to tout his LT-Cage and rhBMP-2, which would become the active ingredient in the ultimate Infuse/BMP-2 product, he encountered some drawbacks to his goal of promoting his and Medtronic’s products, which arose from the policy of certain industry journals, including the journal *Spine*, which followed industry standards before printing peer-reviewed material. See article in the journal *Spine*, published in 2000.

409. Not only were the drawbacks related to industry publishing standards, but the National Consumer Health Information and Health Promotion Act of 1976 enacted certain provisions at 42 U.S.C. § 300u, et seq., whereby the Federal Government had entered the field of

medical research publication. Such standards promulgated by the Secretary of the predecessor to the U.S. Department of Health and Human Services required that applications for grants and contracts must be subject to "appropriate peer review." See 42 U.S.C. § 300u-1.

410. The drawbacks encountered with the peer-reviewed *Spine* article were as follows:

- a. Attribution that the study was "sponsored by Medtronic Sofamor Danek, Inc.;"
- b. The study was conducted under FDA regulations, and was "...designed as a prospective, multicenter, nonblinded, randomized, and controlled pilot study;" and
- c. It was accompanied by a cautionary comment, or Point of View, which minimized the exuberance and import of the article.

411. In the article, BMP-2 was touted by Zdeblick and the co-authors as the potential realization of a dream of Dr. Marshall Urist, a revered pioneer in the industry and discoverer of BMP, where it closed with the following: "...it is encouraging to note that Marshall Urist's seminal observation made more than 34 years ago may finally come to clinical fruition."

412. In the Point of View, a Dr. John O'Brien of London questioned whether there could be long-term problems associated with the product. He treated Zdeblick's study with caution and pointed out that simple plaster of Paris has achieved the same or similar results more than 50 years prior. He posited that, "[p]erhaps vascularization...fixation procedures are as important as the biochemical composition of the 'filler.'"

413. Vascularization is achieved through removal of the disc material between two vertebral bodies and then the scraping of the surfaces of the vertebral bodies in a fusion procedure; fixation is the process of securing the motion segment through medical hardware. In other, if

the alternative proposed by Dr. O'Brien proved to achieve equivalent or better results,

Zdeblick and Medtronic's Infuse/BMP-2 products would be useless and unnecessary.

414. Certain efforts would follow in an attempt to alleviate the drawbacks encountered with the 2000 *Spine* journal article.

415. In 2002, Dr. Zdeblick was installed as the sole editor-in-chief of a medical journal known prior to his installation as the *Journal of Spinal Disorders*. Prior to his installation, the journal enjoyed a fourteen-year history under the co-editorship of Dr. Dan Spangler and Dr. Tom Ducker. Once installed, Dr. Zdeblick successfully supplanted Drs. Dan Spangler and Tom Ducker and became the sole editor-in-chief, a position which would enable him to have greater control and would aid his participation in the fraudulent scheme.

416. During this same time period, Dr. Zdeblick also enjoyed a position on the associate editorial board of the medical journal *Spine*, the leading publication covering all disciplines relating to the spine.

417. In one of Dr. Zdeblick's actions as editor-in-chief, he set about re-purposing the journal in a way that would aid him in the furtherance of the fraudulent scheme through the streamlining of the publication process.

418. In furtherance of the fraudulent scheme, Dr. Zdeblick re-purposed the journal and renamed it the *Journal of Spinal Disorders and Techniques* (JSDT), announcing that the new journal was "entering a new partnership with *Spine*." As part of this partnership, *Spine* would "continue to function as a broad-based scientific journal" tailored to both clinicians and scientists. However, the *Journal of Spinal Disorders and Techniques* would be directed solely to physicians in clinical practice.

419. Dr. Zdeblick's stated goal was "to provide a forum for up-to-date techniques...", and in furtherance of that goal, Dr. Zdeblick announced that his journal would publish Class II or better clinical articles but would "occasionally accept cutting edge articles with less than one-year follow-up." To justify this streamlined process, Dr. Zdeblick claimed as his goal the ability of his journal "to keep up with the fast pace of progress in the treatment of spinal patients."

420. Arm-in-arm with Medtronic and others, Dr. Zdeblick would in short order abuse his position of trust as the editor-in-chief of JSDT.

421. In the October 2002 edition, JSDT published an article entitled, "Anterior Lumbar Interbody Fusion using rhBMP-2 with Tapered Interbody Cages." This article was co-authored by, among others, Curtis A. Dickman, M.D., who was a developer of Medtronic's PYRAMID plate and who has been paid significant sums by Medtronic through royalty agreements, consulting agreements, and education training and speaking agreements.

422. In addition to his interest in the PYRAMID plate, Dr. Dickman had assisted Medtronic in the approval process for Infuse/BMP-2. As part of the pre-approval hearing process, Dr. Dickman and his Barrow Neurological Associates Group of Phoenix, Arizona had submitted a letter to the meeting of the FDA's Orthopedics and Rehabilitation Devices Advisory Panel, which met on January 10, 2002. In that letter, Dr. Dickman represented that "approval of BMP would provide a significant advance for patient outcome and satisfaction following spinal fusion."

423. In the October 2002 issue of JSDT touting the benefits of Infuse/BMP-2, Zdeblick and others failed to disclose their financial ties to Medtronic, though industry standards require such acknowledgement. Not only did Dr. Zdeblick fail to disclose that he profited from each

and every surgery which Infuse/BMP-2 was used through rights in the exclusive delivery vehicle, his LT-Cage, but no reference whatsoever to their financial ties to Medtronic was made either by Dr. Zdeblick or Dr. Dickman.

424. For years, the recognized gold standard for spinal bone grafts has been the use of autogenous bone, or bone harvested from the patient's own iliac crest, or hip bone. Medtronic designed to have its Infuse/BMP-2 product supplant autogenous bone as the gold standard in the medical community, and utilized false statements, a fraudulent enterprise and the support of Federal funds to do so.

425. As part and parcel of Medtronic's fraudulent scheme, the October 2002 study was published in Dr. Zdeblick's journal three months after Medtronic received FDA approval for Infuse. As the article shows, it was actually received on March 28, 2002 or after Dr. Zdeblick had accomplished installment as the editor-in-chief, and was accepted by Dr. Zdeblick's journal for publication on July 30, 2002.

426. At the same time Dr. Zdeblick's journal was publishing the initial article on Infuse, Dr. Zdeblick was already finalizing and preparing for subsequent publication a follow-up article to tout Infuse potentially as the new gold standard. A second article, co-authored by Dr. Zdeblick and two other co-authors of the original article, was entitled "Is Infuse Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials using the LT-Cage Lumbar Tapered Fusion Device."

427. This second article was published in Vol. 2 of 2003 and once again, there was no mention of Dr. Zdeblick's financial ties to Medtronic.

428. This second article would serve as the second covert advertisement for the Infuse product, and the article states that “the purpose of our analysis was to investigate the potential statistical superiority of Infuse bone graft to autograft...”

429. This second article went on to announce the July 2002 FDA approval of rhBMP-2.

430. This article included as an “acknowledgment” an expression of gratitude to the physicians “who provided patients for this study and to the clinic research group at Medtronic Sofamor Danek for their help in data collection and statistical analyses.”

However, the article still failed to advise the medical community that some or all of the authors reaching these conclusions touted as monumental had direct financial interests tied to those conclusions.

431. Rather, the failure to report these clear conflicts of interest on the part of those holding positions of trust both within the medical community and over patients was part of Medtronic’s fraudulent enterprise. However, unchecked by appropriate peer review, Medtronic was able to systematically accomplish their goals.

432. In its 2003 Annual Report, and without recognizing that Zdeblick was being paid by Medtronic, Medtronic cited to Zdeblick’s 2003 as reporting that Infuse “...may become the new gold standard in spinal fusion surgery.”

433. By its 2006 Annual Report, if not earlier, Medtronic had removed all doubt, declaring that after its introduction in 2002, “Infuse Bone Graft quickly became the gold standard for certain types of lumbar fusion.”

434. Medtronic’s fraudulent scheme was successful and resulted in a revenue stream ranging from 700 to 900 million dollars per year.

435. It has been reported that around the same time these stories about Infuse were published, editors at the Spine Journal began receiving complaints from doctors around the country who were pointing out contradictions between papers published by doctors with financial ties to Medtronic and other data involving Infuse complications.' See *Journal Sentinel* article of John Fauber.

436. Through the use of these sham consulting, royalty and education/training agreements with its physician agents in this fraudulent enterprise, Medtronic has reaped windfalls in the billions of dollars. Medtronic has used this fraudulent enterprise and civil conspiracy to drive its vast profits and enhance its market position beyond that which it would have realized without engaging willfully, knowingly and potentially deliberate, conscious, or reckless indifference in the fraudulent enterprise and fraudulent concealment. See Mississippi case.

437. Defendants had full knowledge of all these facts pertaining to Medtronics.

VI. FDA PUBLIC HEALTH NOTIFICATION

438. On July 1, 2008 the FDA issued a Public Health Notification entitled "Life-Threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion."

439. This notification was sent to health care practitioners all across the United States warning of the complications associated with BMP-2, specifically when used in the cervical spine.

440. In the notification the FDA stated they received at least 38 reports of complications during the prior four years with the use of BMP-2 in cervical spine fusions.

441. The complications were associated with swelling of the neck and throat areas, which resulted in compression of the airway and/or neurological structures in the neck.

442. Some reports describe difficulty swallowing, breathing or speaking and severe dysphagia following cervical spine fusion using BMP-2 products had also been reported.

443. The notification further stated that, "since the safety and effectiveness of rhBMP for treatment of cervical spine conditions has not been demonstrated, and in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies.

444. The Notification further emphasized the importance of fully informing patients of these potential risks and said that patients treated with BMP-2 in the cervical spine should know:

- s. The signs and symptoms of airway complications, including difficulty breathing or swallowing, or swelling of the neck, tongue, mouth, throat and shoulders or upper chest area
- t. That they need to seek medical attention immediately at the first sign of an airway complication
- u. That they need to be especially watchful 2-14 days after the procedure when airway complications are more likely to occur
- v. rhBMP-2 (contained in Infuse Bone Graft) has received pre-market approval for fusion of the lumbar spine in skeletally mature patients with degenerative disc disease at one level from L2-S1 and for healing of acute, open tibial shaft fractures stabilized with an IM nail and treated within 14 days of the initial injury.

445. Additionally, BMP is not approved in any manner for use in patients who are skeletally immature (<18 years of age) or pregnant.

446. Dr. Durrani and the Hospitals ignored ALL of these warnings and used BMP-2 in cervical spine surgeries, children, and those with known compromising factors such as osteoporosis, smoking, and diabetes.

447. Furthermore, the Notification stated that the FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

448. The Hospitals that allowed Dr. Durrani to use BMP-2 in their facilities failed to report any complications resulting from his use of BMP-2.

VII. SENATE FINANCE COMMITTEE REPORT

449. Medtronic's actions did not go unnoticed, and in June of 2011 the Senate Finance Committee began an investigation into the fraudulent actions of Medtronic.

450. Medtronic produced more than 5,000 documents pertaining to 13 different studies of BMP-2 for the investigation.

451. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into Medtronic, which revealed questionable ties between the medical technology company and the physician consultants tasked with testing and reviewing Medtronic products.

452. The investigation revealed that Medtronic employees collaborated with physician authors to edit and write segments of published studies on BMP-2/Infuse without publicly disclosing this collaboration.

453. These fraudulently-produced studies may have inaccurately represented BMP-2's risks and may have placed added weight on the side effects of alternative treatments.

454. The Senate investigation further found that Medtronic also maintained significant, previously undisclosed financial ties with physicians who authored studies about BMP-2, making \$210 million in payments to physicians over a 15-year period.

455. Senator Baucus stated, "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and

benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. Patients everywhere will be better served by a more open, honest system without this kind of collusion.”

456. Senator Grassley stated, “The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and the studies they feature. These publications are prestigious and influential, and their standing rests on rigorous science and objectivity. It’s in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part.”

457. Major findings of the investigation include:

- a. Medtronic was involved in drafting, editing, and shaping the content of medical journal articles authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company’s role in authoring or substantially editing these articles was not disclosed in the published articles. Medical journals should ensure that any industry role in drafting articles or contributions to authors is fully disclosed.
- b. Medtronic paid a total of approximately \$210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.
- c. An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with BMP-2/Infuse in a 2005 *Journal of Bone and Joint Surgery* article.
- d. Medtronic officials inserted language into studies that promoted BMP-2 as a better technique than an alternative by emphasizing the pain associated with the alternative.

- e. Documents indicate that Medtronic prepared one expert's remarks to the FDA advisory panel meeting prior to BMP-2 being approved. At the time, the expert was a private physician but was later hired to be a vice president at Medtronic in 2007.
- f. Medtronic documents show the company successfully attempted to adopt weaker safety rules for a clinical trial studying BMP-2 in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

VIII. YODA STUDY

458. In response to the various controversies surrounding BMP-2/Infuse, including a June 2011 article in the journal *Spine*, the Yale University Open Data Access (YODA) team reached an agreement for Medtronic to provide full individual participant data from all their trials of rhBMP-2 and allow unrestricted independent re-analysis of this data.
459. The YODA study involved research teams at two universities – the University of York and the Oregon Health and Science University.
460. The review focused exclusively on the use of rhBMP-2 in patients undergoing spinal fusion surgery for treatment of degenerative disc disease, spondylolisthesis, or any other relevant spinal condition.
461. The three main objectives of the study were: 1) to examine the potential benefits of BMP-2, 2) to examine the potential harms of BMP-2, and 3) to assess the reliability of the published evidence base.
462. Medtronic submitted data from 17 studies, including 12 randomized controlled trials (RCTs).
463. In total, the YODA study analyzed the data from 1,409 participants.

464. Though the results showed moderate success with fusions as a result of BMP-2, the study found that BMP-2 results in several different complications including: arthritis, implant-related events, retrograde ejaculation, wound complications, and neurological, urogenital, and vascular events.

465. In regard to the alleged tampering with the peer-reviewed studies by Medtronic, the YODA study found that only two out of twenty peer-reviewed journal publications reported a comprehensive list of all adverse events that occurred during the studies.

466. Furthermore, the way in which adverse event data was presented in the literature was inconsistent, and the rationale for presenting some adverse events but not others was rarely clear.

467. The study concluded that for the period up to 24 months after surgery, treatment with BMP-2 increases the probability of successful fusion (according to Medtronic definitions and reports, which the study noted “were subjective so it is not possible to confirm whether reported successful fusions truly were successful” see YODA Study, p. 35) but this does not translate to clinically meaningful benefits in pain reduction, function, or quality of life. The small benefits in these outcomes observed from six months onward come at the expense of more pain in the immediate post-operative period and a possible increased risk of cancer.

468. Even more relevant to the case against Dr. Durrani and the Hospitals is the YODA study’s conclusion that, “[i]t is very important that these findings are expressed clearly and discussed with patients so that they can make informed choices about the type of surgery they would prefer.” *Id.*

469. The University of Oregon Study determined that Infuse/BMP-2 is not better than Autograft, while the University of York study determined that Infuse/BMP-2 offers only a slight and not statistically significant advantage over Autograft.
470. The YODA study concluded that Medtronic “misrepresented the effectiveness and harms through selective reporting, duplicate publication, and underreporting.”
471. Adverse event categories such as heterotopic bone formation, osteolysis, and radiculitis were not included in participant databases or internal reports; therefore, the safety profile was not fully assessed.
472. The YODA study further concluded that Medtronic was involved in drafting, editing, and shaping the content of medical journal articles on Infuse/BMP-2 authored by its physician consultants who received significant amounts of money through royalties and consulting fees from Medtronic. The company’s significant role in authoring or substantively editing these articles was not disclosed in the published articles.
473. Medtronic paid a total of approximately \$210 million to the physician authors of Medtronic-sponsored studies on Infuse from November 1996 through 2010 for consulting, royalty and other arrangements.
474. An email exchange showed that a Medtronic employee recommended against publishing a complete list of adverse events or side effects possibly associated with Infuse in a 2005 *Journal of Bone and Joint Surgery* article.
475. Medtronic officials inserted language into studies that promoted Infuse as a better technique than an alternative procedure by overemphasizing the pain associated with the alternative procedure.

476. Medtronic's actions violated the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has. See United States Senate Committee on Finance, October 2012.

477. Infuse was intended for a single level anterior lumbar interbody fusion performed with all three components in a specific spinal region. The three components are a tapered metallic spinal fusion cage (NOT PLASTIC), a recombinant human (BMP) bone Morphogenetic Protein, and a carrier/scaffold for the BMP and resulting bone. The Infuse product is inserted into the LT-CAGE Lumbar tapered Fusion Device component to form the complete Infuse Bone Graft/LT-Cage Lumbar Tapered Fusion Device. These components must be used as a system. The Infuse Bone Graft component must not be used without the LT-Cage Lumbar Tapered Fusion Device component.

478. BMP-2 is not supposed to be used in minors.

479. BMP-2 is not supposed to be used with smokers and diabetics because of vascular slowing.

480. BMP-2 should not be used with women in child bearing years.

481. BMP-2 is contraindicated for patients with a known hypersensitivity to rhBMP-2 and should not be used in the vicinity of a resected or extant tumor, in patients with active malignancy, or in patients undergoing treatment for a malignancy.

IX. DR. DURRANI AND BMP-2

482. Despite all of these warning signs, Dr. Durrani, with the full knowledge of the Defendants, continued to use BMP-2 in ways not approved by the FDA, or in an "off-label" manner.

483. As early as 2007, Dr. Durrani and UC Health knew there were issues with BMP-2 because insurance companies such as Anthem were refusing to pay for BMP-2.

484. Medtronic provided in writing to Dr. Durrani and CAST the approved uses for Infuse/BMP-2.

485. However, Dr. Durrani and the Defendants continued to use BMP-2 in off-label ways, including but not limited to:

- a. Using BMP-2/Infuse in children, despite Medtronic specifically requiring it be used only in “skeletally mature patients;”
- b. Using it outside the L2-S1 level of the spine;
- c. Ignoring the requirement that BMP-2/Infuse only be used for Grade 1 spondylolisthesis or Grade 1 retrolisthesis;
- d. Not requiring at least six months of non-operative treatment prior to the use of BMP-2/Infuse;
- e. Using BMP-2/Infuse without the required cage;
- f. Not using the “carrier scaffold” in conjunction with BMP-2/Infuse as required;
- g. Using BMP-2/Infuse without proper training despite Medtronic’s warning, “Caution: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.”

486. Dr. Durrani was a paid consultant for Medtronic.

487. According to Dr. Durrani’s own deposition testimony in several cases, Medtronic required one of their representatives to be present in the operating room when its product BMP-2/Infuse is used.

488. Because Medtronic representatives were present in these surgeries, Medtronic knew when Dr. Durrani used BMP-2/Infuse outside the approved uses according to Medtronic's own guidelines.
489. Dr. Durrani was encouraged by Medtronic to obtain peer review and published studies from Medtronic sales representatives to support his use of BMP-2/Infuse.
490. Dr. Durrani was encouraged by Medtronic to be an advocate for his patients and describe how BMP-2/Infuse technology can benefit them.
491. When asked how he got his Medtronic grant, Dr. Durrani responded, "You apply to the Medtronic's corporate and say this is what we want to do, like everybody else in the country applies, and then they come and evaluate the thing and say, "Okay, we think it's worthy. We'll give you the grant."
492. In regard to his role as a Medtronic consultant, Dr. Durrani stated, "If there are certain products that they help us in developing, then they will come to us for a certain consultant role for a certain product development."
493. Dr. Durrani also stated, "I was involved in the development of the minimally invasive spine instrumentation."
494. Dr. Durrani gave conflicting reports on his financial relationship with Medtronic.
495. In a deposition, when asked when his relationship with Medtronic began, Dr. Durrani responded "2000-it's 2003, '04. Something in that category. I'm not sure. It's on the Medtronic website. You can go look at it."
496. Medtronic's website has no information regarding their relationship with Dr. Durrani.
497. In another deposition, Dr. Durrani stated he began his relationship with Medtronic in "2005 or '06."

498. Dr. Durrani also gave conflicting reports on how much compensation he received from Medtronic for his consultation services.

499. In one deposition, Dr. Durrani stated in response to an inquiry as to how much payment he received, "It's a standard compensation. Again, it's on the website, how much they've paid us."

500. Again, this information is not available on the Medtronic website.

501. In another deposition, when asked if he received income from Medtronic, Dr. Durrani replied, "No, I don't."

502. When questioned further if he received a fee as a consultant, he stated, "If you do a work, there is a contractual obligation that they have to pay you. As I told you in my last deposition, they did declare it on their website, so you can actually go on the website and see how much they paid."

503. In another deposition, Dr. Durrani stated that he received, "less than \$10,000 in ten years" from Medtronic.

504. An email dated July 30, 2008 from Medtronic Senior Product Manager Katie Stamps to Dr. Durrani states that she "is in the process of working on the renewal of your [Dr. Durrani's] consulting agreement." As stated, this information is not available on Medtronic's website, nor is any information relating to Dr. Durrani's role as a consultant for Medtronic.

505. A CCHMC packet relating to its Orthopedics department indicated that Dr. Durrani received \$60,000 in grants, contracts, or industry agreements from Medtronic Sofamor Danek in FY 2008.

506. Financial information discovered concerning Dr. Durrani's relationship with Medtronic was found in Dr. Durrani's biography on the website for the Orthopaedic & Spine Institute,

which Dr. Durrani currently operates in Pakistan. The biography states that “Dr. Atiq Dr. Durrani has also received the Clinical Spine Fellowship Grant by the Department of Orthopaedic Surgery which was funded by Medtronic Sofamor Danek with a budget of \$59,170 per year.” See [http://www.osi.com.pk/doctor/dr-atiq-Dr. Durrani-md/](http://www.osi.com.pk/doctor/dr-atiq-Dr.-Durrani-md/).

507. When a request was made to Medtronic regarding its affiliation with Dr. Durrani, the Medtronic Supplier Relations Team stated that Dr. Durrani’s “name [is] not listed in our system.”
508. Medtronic further responded to the Deters Law Firm’s request that the firm would need a “Vendor I.D. Number,” which neither Medtronic nor any other party has provided.
509. David Rattigan, was Dr. Durrani’s main Medtronic representative from Bahler Medical.
510. David Rattigan and Medtronic have the same lawyer. Despite the Deters Law Firm’s willingness to cooperate in scheduling the date for a deposition, they have refused until recently. Mr. Rattigan’s deposition was taken June 5, 2015.
511. In summary, clients of the Deters Law Firm, with the full knowledge and intentional consent of all Defendants, became unsuspecting experiments for real world testing of Medtronic hardware and BMP-2, by and through Dr. Durrani and CAST, who had secret financial connections to Medtronic, improper motives, and submitted false claims. The government paid for many of these improper and unregulated experiments as a result of the false claims made by Dr. Durrani, with the knowledge of Medtronic, under the veil of “medically necessary” surgeries.
512. Despite repeated requests, Medtronic has refused to cooperate in providing any requested information and is actively downplaying their connections to Dr. Durrani.

X. THE DEFENDANTS AND BMP-2

513. The purpose of the background information on the following Defendants and BMP-2 concerning other hospitals is to show the egregious methods, which upon information and belief were used at all hospitals.

514. The Defendants allowed and encouraged these practices by Dr. Durrani for the sole purpose of money and greed.

515. David Rattigan was always present in Dr. Durrani's operating rooms as a representative of Medtronic.

516. David Rattigan's sole job was to deliver the BMP-2/Infuse to the Hospitals and make sure that it was inserted correctly into the patient.

517. David Rattigan's presence in the OR further supports the Defendants awareness of Dr. Durrani's fraudulent use of BMP-2/Infuse.

518. Informed Consent for Surgical or Medical Procedure and Sedation:

It is the responsibly of the attending physician to obtain informed consent prior to the procedure. The patient, or his/her representative, will be advised by his/her physician of:

- a. The explanation of the procedure
- b. The benefits of the procedure
- c. The potential problems that might occur during recuperation
- d. The risks and side effects of the procedure which could include but are not limited to severe blood loss, infection, stroke or death.
- e. The benefits, risks and side effect of alternative procedures including the consequences of declining this procedure or any alternative procedures.
- f. The likelihood of achieving satisfactory results

Completion of the "Consent to Hospital and Medical Treatment" form to examine and treat is NOT sufficient as consent to perform a surgical procedure, invasive procedure, or for medical regimens of substantial risk or that are the subject of human investigation or research.

519. The Defendants had the responsibility to carry out these consent rules.

520. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

521. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

522. Dr. Durrani is a consultant for Medtronic.

523. Defendants did not inform Plaintiffs of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

524. Medtronic, provided in writing to Dr. Durrani the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

525. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

526. BMP-2 is neither safe nor approved for use on children less than twenty-one (21) years of age.

527. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

528. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using

components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

529. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

530. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

531. Dr. Durrani and Children's Hospital personnel did not disclose to Plaintiffs their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

532. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

533. Defendants did not inform Plaintiffs that Dr. Durrani used Infuse/BMP-2 in his surgeries.

534. Plaintiffs would not have allowed BMP-2 to be used by Dr. Durrani in his surgery in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

535. Plaintiffs would not have consented to the use of BMP-2 in Plaintiff's body if informed of the risks by Dr. Durrani or any Children's Hospital personnel.

536. The written informed consent of Dr. Durrani signed by Plaintiffs lacked the disclosure of Infuse/BMP-2's use in his procedures.

537. Plaintiffs never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani or any Children's Hospital personnel.

538. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

539. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

540. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

541. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

542. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

TRIGGERS - RETENTION

543. With respect to Dr. Durrani, West Chester/UC Health did not follow their written medical staff policies and procedures under their professional practice evaluation policy.

544. West Chester/UC Health failed to follow the triggers for peer review from January 2009 through May 2013.

545. The following are the triggers for peer review or other actions as provided by West Chester/UC Health to the Deters Law Office in discovery in related litigation and is a list which by their own admission is not exclusive and is a list they produced after full knowledge of the items Dr. Keith Wilkey, Plaintiffs' experts, considered triggers:

- A. Wrong operative procedure performed
- B. Serious injury due to medical device
- C. Procedure performed on wrong patient
- D. Medication resulting in death
- E. Delay in diagnosis
- F. Autopsy not correlated with clinical diagnosis
- G. Delay in treatment resulting in serious injury or death
- H. Alleged abuse or neglect

- I. Unexpected death
- J. Surgical death
- K. Mortality review
- L. Unplanned second surgeon called to OR
- M. MD not credentialed for procedure
- N. Focus review
- O. Incident reports
- P. Contraindication to surgery
- Q. Unintended retention of foreign object in a patient after surgery
- R. Complications from procedure (i.e. readmits, infections, pneumothorax after procedure)
- S. X-ray discrepancies
- T. Returns to surgery
- U. Transfusion not meeting criteria on order sheet
- V. Change in surgery/procedure
- W. Laceration/or perforation/puncture of organ during invasive procedure
- X. Acute MI or CVA within 48 hours of procedure
- Y. Anesthesia complications
- Z. MD without timely response to ED or unit call
- AA. Risk management issues
- BB. Delay in treatment not resulting in serious injury and/or death
- CC. Delay in diagnosis not resulting in injury or death
- DD. Acute blood loss as indicated by procedure

- EE. Appropriate care measures not ordered
- FF. Readmission- complication of previous admission
- GG. Unplanned admission following surgery
- HH. 72 hours returns to ED and readmit same issue
- II. Insufficient documentation
- JJ. BMP-2
- KK. PureGen
- LL. Late dictation or no dictation of operative reports or discharge summaries
- MM. False claim of spondylolisthesis
- NN. False claim of stenosis or its severity
- OO. Performing surgeries on patients whose health condition vitiates surgery:
age, diabetes, obesity, hypertension, mental health issues, etc.
- PP. Shanti Shuffle- Dr. Shanti being forced to do an entire surgery for Dr.
Durrani by Dr. Durrani without the patient's knowledge.
- QQ. No hospital consents or improper CAST consents
- RR. Failed Hardware
- SS. Performing surgery not qualified to perform
- TT. Dura tear
- UU. Having hardware which should be removed, which is never removed
- VV. Not using the proper cage with BMP-2
- WW. Ignoring radiology results
- XX. Misrepresentations to primary care physicians

546. Dr. Keith Wilkey, a board certified spine expert, has reviewed over 213 patient charts at West Chester of Dr. Durrani and signed 213 affidavits of merit as required under CR10 of Ohio Rules of Procedure to file a medical malpractice case and based upon these reviews over 500 events triggers place which would have required action against Dr. Durrani by West Chester. Defendants intentionally took no action.

547. In 2008, insurance companies became much more selective in what they would authorize for payment. They started only paying for spinal surgeries that were highly indicated, meaning there was rock solid medical evidence to support their necessity for treatment of patients.

548. Certain diagnoses such as spondylolisthesis and severe spinal stenosis have good literature support for complicated lumbar fusion procedures with instrumentation, highly indicated procedures with good outcomes which result in; more pay for Durrani. Dr. Durrani would use these extensively. The data shows Dr. Durrani falsely claimed spondylolisthesis diagnosis 95% of the time.

549. Most of the surgeries Dr. Durrani actually performed were a lesser indication; mainly degenerative disc disease with lesser amounts of spinal stenosis which insurance companies will not usually pay for the more expensive spinal fusion; less pay for Dr. Durrani. This is why Dr. Durrani would claim the conditions of spondylolisthesis.

550. Surgeons have to obtain advanced authorizations from the patient's insurance carrier prior to doing the surgery. If surgeons are requesting to do a surgery with a lesser indication, most of the time it is denied unless the requesting surgeon can convince a "peer surgeon" of the need to do the bigger surgery and demonstrate why this case is an exception to their policies. That takes time and the peer has access to the patient's whole medical record. That peer reviewer could easily have discovered the fraudulent diagnoses Durrani was claiming.

551. Beginning in 2009, Dr. Durrani lied much more often to avoid the whole process and possibility of discovery by the insurance companies.

552. Dr. Durrani didn't do his operative reports on time so as to assist his cover-up of the fraudulent diagnoses.

553. Government has given hospitals incredible power to act as the "watch" for patient's safety and well-being, but with that power comes responsibility.

554. West Chester Hospital had the duty to monitor its physicians via the peer review process and at least on paper, they had the process in place.

555. In that process, West Chester had several "triggers" established which would have resulted in an in-depth peer review. Triggers don't have to be events or behaviors that are malpractice, but are designed to be even more sensitive.

556. Most of those triggers are suggested by the government such as complications and return to surgery. However, hospitals are supposed to adjust their triggers for the individual physicians depending on their practice type and behaviors. This is to insure that the hospital has meaningful triggers for each physician. It wouldn't make sense to monitor operative reports for an internist that doesn't operate. It would make more sense to look at his discharge summaries.

557. For Dr. Durrani, meaningful triggers would have been items tracked during the medical record review of the malpractice claims. Although complications such as hardware failure, nonunion and revision are not mandated by the government for hospital triggers, any responsibility peer review committee should have reviewed Dr. Durrani's results and adjusted the triggers for Dr. Durrani to reflect his higher than normal complication rate in these areas. Other areas tracked should have included his off-label and contraindicated use of Infuse and PureGen.

558. Defendants failed to act upon an overwhelming amount of material. There were over 591 individual triggers that were ignored by West Chester. That is overwhelming and unforgivable for a hospital to allow, given the power they had to protect their patients from harm.

559. On peer review, they are asked to identify and assist with the removal of known incompetence. A surgeon's duty on the peer review panel is to protect patients from illegal operations. Surgeons look for false and fraudulent diagnoses plus fictitious medical treatment.

560. The peer review committee is asked to sit on the committee for usually two years at a request.

561. West Chester Hospital had bylaws based upon the joint commission accreditation of healthcare organizations known as "The Joint Commission." The principles of the initial credentialing that allowed Dr. Durrani to start operating and mechanisms available to the hospital to stop him from harming other patients a basically equivalent. There are some "minor" variations between state laws but for the most part, they are the same. An example would be the "process" called summary suspension, after it becomes clear of a physician's incompetence, the mechanism to remove him are the same everywhere. Therefore, the situation regarding West Chester and Dr. Durrani are unique only in their depth and degree to which Dr. Durrani's egregious behavior was allowed to harm patients before he was stopped only by the filing of over one hundred lawsuits.

562. The credentialing and peer review work is kept secret from the public.

563. Credentialing is a very lengthy application where 40 to 100 pages of documents are required. Each of these have to be verified by the credentialing personnel from the hospital and then a committee member is assigned to do a further background check into these applicants past work to include calling references, hospitals and training programs.

564. Within some broad limits, one can probe very deep into the past of an applicant because the applicant signs multiple disclosure agreements before the background check. This insures that if needed, the peer review can make good recommendations to the committee chairperson.

565. Given Dr. Durrani's behavior and clinical problems in Cincinnati at the time he was applying for credentials at West Chester, phone calls should have been made regarding Dr. Durrani's past work history, particularly at Children's Hospital. Another "red flag" that Dr. Durrani would have had was the fact he was not board certified by the American Academy of Orthopedic Surgeons or a member of the North American Spine Society.

566. Being board certified and a member of a specialty society is a good way for a hospital to have some external quality check for the applicant. If the applicant doesn't have those in their packet, it's a "red flag" and the reviewer for the committee has to be vigilant and do extra digging.

567. If West Chester and Defendants had called and received reports not favorable to Dr. Durrani the information would be confidential and administration could still take a chance and convince the physicians of the credentialing committee and MEC to allow the privileging anyway. Privileging under these circumstances is usually granted by the staff with very strict terms and the physician would be on a very "short leash."

568. If this happens, the physician is put on a strict probationary period with any violation of the bylaws resulting in termination and databank report is filed.

569. Dr. Durrani was incompetent and he should have had an immediate summary suspension and a National Practitioner's Databank report should have been filed after a fair hearing confirmed the initial suspension. This report would be the only way the public would know that Dr. Durrani was found to be incompetent by his peers at West Chester. This report did not

happen and the hospital administration officers, Board members and Defendants were protecting Dr. Durrani from the usual process of peer review.

570. The hospital administration has considerable control of the peer review process. They rightly claim the actual process of reviewing the patient's records and voting on the issue at hand is done by the hospital medical staff. The administration controls all the remaining variables; the physicians assigned to the committee are assigned to review the individual case, which physician is reviewed and the selecting "triggers" for the process and, the "assistants of the committee" that monitor physicians on a daily basis are all hospital employees.

571. According to a review report of Dr. Durrani performed by Dr. Keith Wilkey, 8 of 16 patients OR reports were not done in a thirty-day window, it included a lot of fictitious, fraudulent and false diagnoses, two contraindicated use of Infuse used in minors, one cancer after Infuse and several novel surgeries—VATS, AxiaLIF, DLIF. The results of this peer review speak for itself. Had this study been completed, there is no way to conclude otherwise that Dr. Durrani was incompetent. He should have been summarily suspended before the study was done to protect future patients. The peer review should have reported to the MEC and then Dr. Durrani should have been suspended until a hearing at the MEC level confirmed or denied the summary suspension. A databank report would have been required to be filed by West Chester.

572. West Chester's bylaws clearly state the requirement that OR reports be done within 30 days from the completion of the surgery. Without exceptions, physicians get written notification of their delinquent records and are given anywhere from seven to ten days to correct the deficiency. If the charts are not dictated within that time limit, the physician is summarily suspended and the case is sent to the MEC for their review. This process may be repeated one or two more times, but usually within a six-month period, the delinquent physician has their

privileges revoked and a databank report filed. Dr. Durrani was given an exception for over four years.

573. Defendants willingly overlooked illegal operations. Dr. Durrani gave false or exaggerated and fraudulent diagnoses plus fictitious medical treatment. His surgical outcomes were horrible.

574. The hospital has to disclose the OR reports and the report included the time and the date of the dictation, to which the delay from the surgery date can be determined. West Chester had to disclose emails between the hospitals and Dr. Durrani. In one email from the CEO, Defendant Joseph to Dr. Durrani, the CEO acknowledges that they knew of Dr. Durrani's dictation violations. Therefore, they had actual knowledge of Dr. Durrani's violations and cannot claim a statutory presumption of immunity from negligent credentialing.

575. The Joint Commission sets the standard and hospital compliance isn't controlled by the state. Hospitals have to have ongoing physician monitoring in place to satisfy the accreditation requirements. Good hospitals require a medical staff that is willing and able to monitor itself through Practitioner Performance—ongoing professional practice evaluation “OPPE.”

576. Since 2009, the Joint Commission has required hospitals, through its medical staff, to conduct an ongoing professional practice evaluation of every privileged practitioner at the hospital, without exception. There are three essentials to OPPE: it must measure certain things (for surgeons, surgical complications and treatment patterns), the measures must be collected and assessed (periodic chart review, observation, discussion with other doctors and nurses), and finally the medical staff must act on its findings (focused professional performance evaluation instituted.) It is a confidential process.

577. Due to the confidentiality, Dr. Durrani's OPPE from the hospital is not available but because West Chester is joint commission accredited and they supposedly meet all their requirements, it is safe to conclude the OPPE process was done two or three times on Dr. Durrani. Once he started at West Chester and then before his re-credentialing every two years. He either resigned, did not reapply, or was revoked around his four-year re-credentialing.

578. There is another instance where West Chester administration should have known about the other Dr. Durrani issue in that if the OPPE found problems, the MEC should have required a FPPE, which is an in-depth review with the possible requirement for corrective action, summary suspensions, and recommendation of limitation or termination of privileges. If a FPPE was ongoing and Dr. Durrani resigned during this process, a Databank report should have been filed, which didn't happen.

579. Anytime an event occurs that is significant, called a "trigger" OPPE or an FPPE can be conducted, and given Dr. Durrani's poor performance that should have occurred given a medical staff that was diligent in their duties. The administration had multiple warnings from the medical staff about Dr. Durrani. They knew he was bad and ignored that fact.

INFUSE/BMP-2

580. Dr. Durrani oftentimes used BMP-2 "off-label" when performing surgeries.

581. BMP-2 is manufactured, marketed, sold and distributed by Defendant Medtronic under the trade name "Infuse."

582. Dr. Durrani is a consultant for Medtronic.

583. Defendants did not inform Plaintiff of Durrani's financial interest, conflicts of interest or consulting arrangement with Medtronic.

584. Medtronic, provided in writing to Dr. Durrani and CAST the approved uses for BMP-2, the substance also referred to as Infuse, which is a bone morphogenic protein, used as an artificial substitute for bone grafting in spine surgeries.

585. BMP-2 is not approved by the Food and Drug Administration for use in the cervical and thoracic spine.

586. BMP-2 is neither safe nor approved for use on children less than twenty-one (21) years of age.

587. For use in spinal surgery, BMP-2/Infuse is approved by the FDA for a limited procedure, performed on a limited area of the spine, using specific components. Specifically, the FDA approved Infuse for one procedure of the spine: Anterior Lumbar Interbody Fusion ("ALIF" or "Anterior" approach); and only in one area of the spine: L4 to S1; and only when used in conjunction with FDA-Approved Components: LT-CAGE Lumbar Tapered Fusion Device Component ("LT-CAGE")

588. Use of Infuse in cervical or thoracic surgery, or use through the back (posterior), or side (lateral), or on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

589. When used off-label, Infuse frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

590. The product packaging for BMP-2/Infuse indicates it causes an increased risk of cancer four (4) times greater than other bone graft alternatives.

591. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose to Plaintiff their intent to use BMP-2/Infuse, and further, did not disclose their intent to use BMP-2/Infuse in a way not approved by the FDA.

592. Dr. Durrani used BMP-2 in Plaintiff in a manner not approved by Medtronic or the FDA.

593. Plaintiff was not informed by Defendants that Dr. Durrani used Infuse/BMP-2 in her surgery.

594. Plaintiff would not have allowed BMP-2 to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA or Medtronic, Infuse/BMP-2's manufacturer.

595. Plaintiff would not have consented to the use of BMP-2 in her body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

596. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Infuse/BMP-2's use in her procedures.

597. Plaintiff never received a verbal disclosure of Infuse/BMP-2 from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

598. Medtronic specifically required Infuse/BMP-2 only be used in "skeletally mature patients" with degenerative disc disease.

599. Medtronic required at least six (6) months of non-operative treatment prior to use of Infuse/BMP-2.

600. Dr. Durrani regularly used Infuse/BMP-2 without this six (6) month non-operative treatment.

601. Medtronic required BMP-2 always be used in conjunction with a metal LT cage.

602. Dr. Durrani regularly used BMP-2 without a proper LT cage in his surgeries.

PUREGEN

PUREGEN NARRATIVE

PUREGEN BACKGROUND

603. PureGen Osteoprogenitor Cell Allograft (PureGen) is a highly concentrated, pure population of Early Lineage Adult (ELA) stem cells that originates in bone marrow and is collected from live, healthy donors.

604. PureGen is harvested from living human beings under the Stem Cell Collection Program administered by the Food and Drug Administration (FDA) and is defined as both a “biologic” by 42 U.S.C. 351(i) and a “drug” as defined by U.S.C. 321(g).

605. PureGen’s purpose was to facilitate bone fusion by mimicking the regenerative environment of youthful tissues by increasing the concentration of stem cells available to repair tissue and build bone.

606. When used off-label, as Dr. Durrani often did, biologic bone allograft frequently causes excessive or uncontrolled (also referred to as “ectopic” or “exuberant”) bone growth on or around the spinal cord.

607. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and cramps in limbs.

608. Alphatec Spine, Inc. is a corporation under the laws of California, and jointly developed and distributed PureGen in the State of Ohio.

609. Alphatec Holdings, Inc. is a holding corporation formed under the laws of Delaware with no operations separate from the holding of other companies which owns Alphatec Spine, Inc.

610. Dirk Kuyper was President and CEO of Alphatec Holdings, Inc. from February 2007 to August 2012.

611. Parcell Laboratories, LLC is organized under the laws of Delaware and jointly developed Puregen.

612. Alphatec and Parcell co-developed the product "PureGen", and both expected PureGen would be initially limited in application.

613. PureGen is produced and distributed by Alphatec Spine, LLC, a division of Alphatec Holdings.

614. PureGen was entered into 3 clinical trials by Alphatec on or around February 9, 2011 which were scheduled to last until September of 2013.

615. The study population were 50 male/female subjects 18 years and older suffering from symptoms of cervical degenerative disc disease in one to four contiguous levels between C3 and T1.

616. The clinical trial required:

a. Inclusion

- i. Age over 50
- ii. Side-by-side use of Puregen and Autologous bone in the same patient for radiographic comparison
- iii. Symptomatic lumbar degenerative disc disease in up to 2 contiguous levels between L1 and S1
- iv. Subjects with back and/or leg pain indicated for posterior stabilization with or without decompression at any level and posteriolateral fusion
- v. Unresponsive to conservative treatment for at least 6 months
- vi. Radiographic evidence of primary diagnosis

b. Exclusion:

- vii. No healthy volunteers permitted
- viii. More than two levels requiring posteriolateral fusion (PLF)
- ix. Spondylolysis greater than Grade 1
- x. Prior failed fusion surgery at lumbar level(s)
- xi. Systemic or local infection in the disc or cervical spine, past or present
- xii. Active systemic disease
- xiii. Osteoporosis, Osteomalacia, or other metabolic bone disease that would significantly inhibit bone healing
- xiv. Use of other bone graft, Bone Morphogenic Protein (BMP), or bone graft substitutes in addition to or in place of those products specified
- xv. BMI greater than 40
- xvi. Use of post-operative spinal cord stimulator
- xvii. Known or suspected history of alcohol and/or drug abuse
- xviii. Involved in pending litigation or worker's compensation related to the spine
- xix. Pregnant or planning to become pregnant during the course of the study
- xx. Insulin-dependent diabetes mellitus
- xxi. Life expectancy less than duration of study

- xxii. Any significant psychological disturbance that could impair consent process or ability to complete self-assessment questionnaires
- xxiii. Undergoing chemotherapy or radiation treatment, or chronic use of oral or injected steroids or prolonged use of non-steroidal anti-inflammatory drugs
- xxiv. Known history of hypersensitivity or anaphylactic reaction to dimethyl sulfoxide (DMSO).

617. All 3 clinical trials were "Terminated" before any results were produced.

618. Alphatec and Parcell saw this limited approval for clinical trials as an opportunity to market PureGen without premarket approval, 510K clearance, an exception to the Food Drug and Cosmetic Act, meeting the humanitarian device exception, investigational new drug (IND) application, or other permission to market PureGen, all in violation of the Food Drug and Cosmetic Act.

619. Alphatec and Parcell began a course of conduct designed to expand the application of PureGen by end users in excess of the approved clinical trial of PureGen. This course of conduct utilized fraud, false statements, material misrepresentation, and deceit in order to broaden the sales of PureGen beyond that which the usual acceptance within the scientific community or regulatory approval would otherwise allow.

620. The Food and Drug Administration (FDA) conducted an inspection of Parcell Laboratories between February 9-14, 2011.

621. After the inspection, the FDA responded quickly to the unlicensed marketing of the device PureGen by warning that PureGen was not the subject of an IND application nor a valid biologics license with a letter dated June 23, 2011.

622. The letter stated that the cells used in the production of PureGen were human cells, tissues, or cellular and tissue-based products (HCT/Ps) as defined in 21 CFR 1271.3(d).

623. Based on this analysis, the FDA determined that PureGen was a drug and biological product as defined in the Federal Food, Drug and Cosmetic Act.

624. According to the Public Health Service Act, a valid biologics license is also required to introduce a biologics device to the market.

625. Alphatec Spine did not acquire a valid biologics license to enter a biologics product into interstate commerce, in violation of 21 U.S.C. 355(a); 42 U.S.C. 262(a).

626. The FDA stated that PureGen, “does not meet all of the criteria in 21 CFR 1271.10(a) and therefore is not regulated solely under section 361 of the Public Health Service Act and the regulations in 21 CFR Part 1271. Specifically, the product does not meet the criterion in 21 CFR 1271.10(a)(4)(ii)(b) because the product is dependent on the metabolic activity of living cells for its primary function.”

627. As a result, a valid biologics license was required, which was never obtained by Alphatec or Parcell labs in regards to PureGen. Defendants knew all this.

628. Given this lack of a valid biologics license, the FDA determined that the marketing of PureGen violated both the Federal Food, Drug and Cosmetic Act and the Public Health Service Act.

629. In a statement to the press approximately a week after receiving the FDA Letter, Alphatec President Dirk Kuyper stated, “Both Alphatec Spine and Parcell Laboratories are fully

committed to work closely and collaboratively with the FDA to address the questions related to the PureGen Product. We look forward to discussing the PureGen product with the FDA and sharing our clinical outcomes to date.” See article “Alphatec comments on FDA’s letter regarding PureGen product for spinal fusion procedures”, Spinal News International, July 28, 2011, attached as Exhibit E.

630. No such cooperation by Alphatec and Parcell labs occurred and no clinical outcomes were shared with the FDA as all clinical trials of PureGen were “Terminated” and no data was released as to the findings.

631. In fact, Alphatec and Parcell responded to this letter by continuing to market PureGen in an unlicensed manner until Alphatec finally acknowledged the letter in or around February 2013, almost two years after receiving the letter, by stating it disagrees with the FDA’s classification of PureGen as anything other than a tissue product – despite the clinical trial approval listing PureGen as “Biological: PureGen Osteoprogenitor Cell Allograft”.

632. Furthermore, according to sales representative, Thomas Blank, Alphatec falsely informed distributors of PureGen that they “resolved” the issues addressed in the FDA letter, did not have to take PureGen off the market and it was “ok” for their distributors to continue marketing and selling PureGen.

633. Despite the approval for the clinical trial of PureGen which limited enrollment to 50 patients, Alphatec advertised in its 2012 Annual Report that PureGen had been implanted in over 3,500 patients.

634. PureGen further stated that it had been placed in these 3,500 patients with “no adverse events related to the product”, despite no study, statistics or information to back up such a claim.

635. This 2012 annual report also identified PureGen as a biologic.

636. In the First Quarter of 2011, Alphatec Spine attributed part of its 40.9% increase in revenue to the PureGen product. See Becker's Spine Review, Alphatec Spine Reports \$49.7M in Q1 Revenue, 40.9% Increase, May 5, 2011, attached as exhibit H.

637. Eventually, after PureGen had been unlawfully implanted in thousands of patients, Alphatec and Parcell conceded that PureGen is a tissue product and a biologic and stopped shipping PureGen in February of 2013.

PUREGEN AND OHIO LAW

638. It is the position of the Deters Law Firm that the distribution and use of PureGen by Dr. Durrani, Evolution Medical, Alphatec Spine, Inc., and West Chester/UC Health by Defendants is in violation not only of Federal Law as outlined in the FDA's letter, but Ohio State Law as well.

639. Ohio Revised Code 3715.65(A) states that "No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the Federal Food, Drug and Cosmetic Act, 52 Stat. 1040 (1938), 21 U.S.C.A. 301". Defendants violated this provision.

640. A "New Drug" is defined as "Any drug the composition of which is not generally recognized among experts by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." Ohio Revised Code 3715.01(9)(a).

641. PureGen's status as a Biologic further supports the classification of a drug under the FDA and Ohio Law: "A "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings (Public

Health Service Act Sec. 351(i)). Additional interpretation of the statutory language is found in 21 CFR 600.3. Biological products also meet the definition of either a drug or device under Sections 201(g) and (h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).” See <http://www.fda.gov/ICECI/Inspections/IOM/ucm122535.htm>.

642. It is the position of the Deters Law Firm that PureGen is a drug as defined in ORC 3715.01 and that its distribution before FDA approval was in violation of ORC 3715.65(A). The Defendants with full knowledge and intent violated this statute.

PUREGEN AT THE HOSPITALS

643. On October 10, 2011, UC Health began purchasing PureGen from Alphatec. Thomas Blank was an employee of Innovative Medical Consultants, LLC and a sales representative, seller, marketer, and distributor of PureGen for the Northern Kentucky/Cincinnati area.

644. In his professional capacity, Thomas Blank was present during most, if not all, of the surgeries at issue where PureGen was secretly implanted into various Plaintiffs without informed consent or permission.

645. Thomas Blank worked directly with Alphatec Spine, Inc. and Defendants in the marketing and distribution of PureGen.

646. Additionally, Thomas Blank is a shareholder in Alphatec Spine, Inc.

647. On May 10, 2012 Evolution Medical, LLC, a physician owned distributorship (POD), owned in part (at least 40%) by Dr. Durrani and incorporated in Delaware, received a Kentucky Certificate of Authority.

648. Around this time, Thomas Blank began to work with Evolution Medical in the marketing and distribution of PureGen, in addition to his dealing with Alphatec Spine, Inc.

649. On July 20, 2012, UC Health with the full knowledge and consent of Defendants began purchasing PureGen from Evolution Medical, LLC.

650. The purchase of PureGen, the logistics of the billing, the bills of lading, the receiving and handling of PureGen for West Chester Hospital was handled by UC Health Purchasing.

651. The Defendants tracked West Chester/UC Health's purchases of PureGen from Evolution medical.

652. Specifically, Thomas Blank would provide the materials from Alphatec related to the use and approval of PureGen to Dwayne Brown on behalf of UC Health, who would request PureGen based on the amounts requested by Dr. Durrani and other doctors who used the product.

653. After the UC Health reps approved the use of PureGen, Thomas Blank and his associate Toby Wilcox would order the product, typically in bulk, and draft the requisite billing documents.

654. The PureGen ordered would be stored on site at WCH in the freezer of the operating rooms.

655. In addition to Dr. Durrani, other doctors at WCH used PureGen, including Dr. Chunduri, Dr. Curt and Dr. Shanti.

656. Defendants would purchase and allow these doctors to use a substance not approved by the FDA in patients without their informed consent.

657. Though WCH and UC Health do have patients fill out "informed consent" forms, no mention of PureGen or its non-FDA approved status is mentioned on these forms.

DR. DURRANI AND PUREGEN

658. In one of the few depositions taken of Dr. Durrani before his flight from the country he stated that PureGen is "essentially stem cells" and that he "used to use [PureGen] for a certain

amount of time.” Deposition of Dr. Durrani in *Brenda Shell v. Durrani*, p. 25-26, attached as Exhibit N.

659. This “certain amount of time” was approximately 3 years between 2010 and 2013, all while PureGen remained unapproved by the FDA.

660. Though downplaying his involvement with PureGen, Dr. Durrani, through his illegal POD Evolution Medical, distributed PureGen to West Chester/UC Health with the full knowledge and consent of Defendants.

661. Dr. Durrani and his Evolution Medical co-owner Toby Wilcox and Defendants, knew the Department of Health and Human Services and the United States Senate Finance Committee has released reports on dangers of Physician-owned entities, notably Physician-owned Distributorships (POD’s).

662. Dr. Durrani and Toby Wilcox’s actions through Evolution Medical violated the Anti-Kickback Statute 42 U.S.C. 1320 and Stark Law 42 U.S.C. 1395.

663. Compliance with the Anti-Kickback Statutes is a condition of receiving payment from a Federally-funded healthcare program, and most private insurers have a parallel conditional requirement.

664. The Anti-Kickback Statute prohibits the payment and receipt of kickbacks in return for either procuring or recommending the procurement of a good, facility, or item to be paid in whole or in part by a federal healthcare program. 42 U.S.C. 1320a-7b(b).

665. In violation of 45 C.F.R. 46, and in furtherance of the scheme to feign avoidance of the anti-kickback statutes, Dr. Durrani, CAST, Alphatec and the Defendants experimented on patients by using PureGen in unapproved manners, without the informed consent of the patients,

and subsequently billing their health insurance companies all while concealing the true nature of their actions.

666. Dr. Durrani also had connections with Alphatec as his personal calendar indicates meetings with Dirk Kuyper, President and CEO of Alphatec in 2008.

667. Dr. Durrani experimentally used Puregen bone graft in twenty cervical surgeries, along with as many as 72 thoracic, cervical, and lumbar surgeries, ignoring the limited uses it was approved for in the clinical trials.

668. Dr. Durrani, through his POD Evolution Medical, was essentially "double dipping" in his dealings with PureGen.

669. Dr. Durrani would sell WCH and the other hospitals the PureGen through Evolution Medical and then use and bill for the PureGen in his surgeries.

670. Dr. Durrani and Defendants knew such an arrangement was either unethical and illegal (though still not disclosing the use of PureGen) by having the patients sign an Acknowledgement of Potential Conflict of Interest form.

671. WCH and Defendant also benefited from this arrangement by up charging patients for the PureGen after purchasing it from Evolution Medical and Dr. Durrani.

672. At all times relevant, Dr. Durrani and Defendants was in exclusive control of the amount and ratio of Puregen bone graft that was experimentally implanted into patients.

673. PureGen was and remains unapproved by the FDA for use in humans without an Investigation New Drug ("IND") or experimental informed consent of the patient.

674. Dr. Durrani and Defendants did not receive experimental informed consent from patients, nor did he verify that an IND was obtained.

675. The basic “Informed Consent Forms” Dr. Durrani and CAST did have patients fill out made no mention of PureGen or the fact a non-FDA approved product was being implanted in their body.

676. In fact, Dr. Durrani and Defendants would even conceal the use of PureGen by intentionally withholding it from the billing records, noting on one Pre-Op Code sheet “Do Not Bill” twice in regards to PureGen.

677. Implanting Puregen in any part of the spinal canal without FDA clearance, proper trials, and patient consent is reckless battery and violates the Hippocratic Oath’s statement “I will prescribe regimens for the good of my patients according to my ability and my judgment and never **do harm** to anyone.” It is criminal.

PUREGEN AND OUR CLIENTS

678. What follows are just a few examples of the damage caused Dr. Durrani and the Defendants deceptive and fraudulent use of PureGen in Deters Law Office clients without their consent.

679. A majority of these surgeries occurred AFTER the FDA inspection and subsequent warning on the non-FDA approved status of PureGen.

680. Following the cervical surgeries in which Puregen was implanted, the patients’ pain became far worse and more extreme.

681. The patients attest to difficulty with swallowing unthickened liquid, medications in pill form, routine saliva, and food.

682. Many patients describe a choking sensation felt on a daily basis when swallowing and changes to the tone and audibility of their voice, along with a chronic cough.

683. Following the thoracic and lumbar surgeries, patients attest to increased spinal pain, difficulty with ambulation, numbness and tingling in lower extremities, decreased flexibility.

684. Below are some of the client's experiences since having the PureGen implanted:

685. "I have severe low back pain, stiffness, decreased range of motion and tenderness. Pain radiating to left posterior thigh and right/left lumbar area. Onset months ago after surgery." –

William Hayes

686. "Constant, irritating pain, less intense but still present. Even after two surgeries, I continue to have limited use of my left leg. The pain is ever-present. I am easily fatigued and have severe pain after brief tasks such as cooking dinner, preaching a sermon, even making a bed. Bending over is so painful and produces such instability that my family helps put on my socks and shoes. I require a cane for ambulation, due to left leg weakness and limited range of motion." – Darrell Earls

687. "Severe spin in my neck, arm, shoulder blades. Pressure on my throat making it unbearable to swallow meds and food. Loss of range of motion in my neck and stiffness in back. The pain is so severe that I can no longer sleep laying down. I have to sleep sitting up. The pain in my neck is unbearable most days. The pain runs between my shoulder blades into my chest and in my throat and side of my neck." - Duane Pelfrey

688. "I feel I have lost a lot of the flexibility in my neck and back. I have lower back pain, tightness in neck and shoulders, and have a hard time lifting/standing for long periods of time. When I bend over, I have a hard time straightening back up to an upright position." - Dana Conley

689. "Low back pain radiating into bilateral hips, buttocks, legs and feet. Bilateral leg weakness. Numbness in left foot and toes. Bilateral buttock and posterior thigh muscle spasms.

Burning sensation in right abdomen that radiates around to back. My post-surgery MRI and CT scan showed bony overgrowth into the foramen and into the canal on left at L5-S1.” - Julie Martin

690. “I experience pounding headaches that are far worse than anything prior to surgery. Left leg is numb, painful and swollen, muscle spasms occurring in hip and bilateral legs since surgeries with Dr. Durrani. My whole back, neck and leg hurt so bad I could throw up.” - Tonia McQueary

691. “I have much more pain. Constant right-sided headache, intensity varies but always present. The back of my neck swells. My esophagus feels like it is in a different place. My throat swells.” – Kelly Hennessey

692. As stated, there are just a few examples of clients that have been discovered to have had non-FDA approved PureGen implanted into their bodies without their informed consent, in violation of both Federal and State Law, all with the knowledge of Defendants.

PUREGEN

693. Dr. Durrani oftentimes used Puregen when performing surgeries.

694. Puregen is a product produced by Alphatec Spine.

695. Dr. Durrani was and is a paid consultant for Alphatec Spine.

696. Dr. Durrani has an ownership stake in the Alphatec Spine.

697. Puregen has never been approved by the FDA for any human use.

698. Puregen is now removed from the market for any use.

699. Dr. Durrani used the product Puregen as bone graft substitute similar to Infuse/BMP-2 during spinal surgeries.

700. Dr. Durrani, CAST staff and employees, and West Chester/UC Health personnel did not disclose their intent to use Puregen, nor did they inform Plaintiff that it was a product that was not approved by the FDA for human use.

701. Dr. Durrani used Puregen in Plaintiff in manners not approved by the FDA.

702. Plaintiff was not informed by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel that Dr. Durrani used Puregen in her surgeries.

703. Plaintiff would not have allowed Puregen to be used by Dr. Durrani in her surgeries in a manner that was not approved by the FDA.

704. Plaintiff would not have consented to the use of Puregen in their body if informed of the risks by Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

705. The written informed consent of Dr. Durrani and CAST signed by Plaintiff lacked the disclosure of Puregen's use in her procedures.

706. Plaintiff never received a verbal disclosure of Puregen from Dr. Durrani, CAST staff and employees, or any West Chester/UC Health personnel.

DR. DURRANI COUNTS:

COUNT I: NEGLIGENCE

707. Defendant Dr. Durrani owed his patient, Plaintiffs, the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

708. Defendant Dr. Durrani breached his duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiffs, including but not limited to improper selection

for surgery, improper performance of the surgery, and improper follow-up care addressing a patient's concerns.

709. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care on the part of the Defendant Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: BATTERY

710. Dr. Durrani committed battery against Plaintiffs by performing a surgery that was unnecessary, contraindicated for Plaintiffs' medical condition, and for which he did not properly obtain informed consent, inter alia, by using BMP-2, PureGen and/or Baxano in ways and for surgeries not approved by the FDA and medical community, and by the failure to provide this information to Plaintiffs.

711. Plaintiffs would not have agreed to the surgeries if they knew the surgeries were unnecessary, not approved by the FDA, and not indicated.

712. As a direct and proximate result of the aforementioned battery by Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: LACK OF INFORMED CONSENT

713. The informed consent forms from Dr. Durrani and CAST which they required Plaintiffs to sign failed to fully cover all the information necessary and required for the procedures and surgical procedures performed by Dr. Durrani. Dr. Durrani and CAST each required an informed consent release.

714. In addition, no one verbally informed Plaintiffs of the information and risks required for informed consent at the time of or before Plaintiffs' surgery.

715. Dr. Durrani failed to inform Plaintiffs of material risks and dangers inherent or potentially involved with her surgeries and procedures.

716. Had Plaintiffs been appropriately informed of the need or lack of need for surgery and other procedures and the risks of the procedures, Plaintiffs would not have undergone the surgery or procedures.

717. As a direct and proximate result of the lack of informed consent, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT IV: INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

718. Dr. Durrani's conduct as described above was intentional and reckless.

719. It is outrageous and offends against the generally accepted standards of morality.

720. It was the proximate and actual cause of Plaintiffs' psychological injuries, emotional injuries, mental anguish, suffering, and distress.

721. Plaintiffs suffered severe distress and anguish so serious and of a nature that no reasonable man or woman would be expected to endure.

COUNT V: FRAUD

722. Dr. Durrani made material, false representations to Plaintiffs and their insurance company related to Plaintiffs's treatment including: stating the surgeries were necessary, that Dr. Durrani "could fix" Plaintiffs, that more conservative treatment was unnecessary and futile, that the surgery would be simple or was "no big deal", that Plaintiffs would be walking normally within days after each surgery, that the procedures were medically necessary and accurately reported on the billing to the insurance company, that the surgery was successful, and that Plaintiffs were medically stable and ready to be discharged.

723. Dr. Durrani also concealed the potential use of Infuse/BMP-2 and/or Puregen in Plaintiffs' surgery, as well as other information, when he had a duty to disclose to Plaintiffs his planned use of the same.

724. These misrepresentations and/or concealments were material to Plaintiffs because they directly induced Plaintiffs to undergo her surgery.

725. Dr. Durrani knew or should have known such representations were false, and/or made the misrepresentations with utter disregard and recklessness as to their truth that knowledge of their falsity may be inferred.

726. Dr. Durrani made the misrepresentations before, during and after the surgeries with the intent of misleading Plaintiffs and their insurance company into relying upon them. Specifically, the misrepresentations were made to induce payment by the insurance company, without which Dr. Durrani would not have performed the surgeries, and to induce Plaintiffs to undergo the surgeries without regard to medical necessity and only for the purpose of receiving payment.

727. The misrepresentations and/or concealments were made during Plaintiffs' office visits at Dr. Durrani's CAST offices.

728. Plaintiffs were justified in their reliance on the misrepresentations because a patient has a right to trust their doctor and that the facility is overseeing the doctor to ensure the patients of that doctor can trust the facility.

729. As a direct and proximate result of the aforementioned fraud, Plaintiffs did undergo surgeries which were paid for in whole or in part by their insurance company, and suffered all damages as requested in the prayer for relief.

COUNT VI: SPOILIATION OF EVIDENCE

730. Dr. Durrani willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

731. Dr. Durrani spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

732. Dr. Durrani's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

CAST COUNTS:

COUNT I: VICARIOUS LIABILITY

733. At all times relevant, Defendant Dr. Durrani was an agent, and/or employee of CAST.

734. Dr. Durrani is in fact, the owner of CAST.

735. Defendant Dr. Durrani was performing within the scope of his employment with CAST during the care and treatment of Plaintiffs.

736. Defendant CAST is responsible for harm caused by acts of its employees for conduct that was within the scope of employment under the theory of respondeat superior.

737. Defendant CAST is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

738. As a direct and proximate result of Defendant CAST's acts and omissions, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT HIRING, RETENTION, AND SUPERVISION

739. CAST provided Dr. Durrani, inter alia, financial support, control, medical facilities, billing and insurance payment support, staff support, medicines, and tangible items for use on patients.

740. CAST and Dr. Durrani participated in experiments using BMP-2 and/or Puregen bone graft on patients, including Plaintiffs, without obtaining proper informed consent thereby causing harm to Plaintiffs.

741. CAST breached its duty to Plaintiffs, inter alia, by not supervising or controlling the actions of Dr. Durrani and the doctors, nurses, staff, and those with privileges, during the medical treatment of Plaintiffs at CAST.

742. The Safe Medical Device Act required entities such as CAST to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

743. Such disregard for and violations of federal law represents strong evidence that CAST negligently hired, retained, and supervised Dr. Durrani.

744. As a direct and proximate result of the acts and omissions herein described, including but not limited to failure to properly supervise medical treatment by Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: SPOILIATION OF EVIDENCE

745. CAST, through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

746. CAST, through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

747. CAST's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

748. Although the Ohio Consumer Sales Protection Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

749. CAST's services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

750. CAST omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

751. CAST's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

752. CAST was fully aware of its actions.

753. CAST was fully aware that Plaintiffs were induced by and relied upon CAST's representations at the time CAST was engaged by Plaintiffs.

754. Had Plaintiffs been aware that CAST's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

755. CAST, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

756. CAST's actions were not the result of any bona fide errors.

757. As a result of CAST's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

- a. Loss of money paid
- b. Severe aggravation and inconveniences
- c. Under O.R.C. 1345.01 Plaintiffs are entitled to:

- i. An order requiring that CAST restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;
- ii. All incidental and consequential damages incurred by Plaintiffs;
- iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred.

COUNT IV: FRAUD

758. Upon information and belief, Plaintiffs believes the bills requested by Plaintiffs will indicate that CAST falsely represented that Plaintiffs' surgery was appropriately indicated, performed, and medically necessary in contra-indication of the standard of care.

759. CAST sent out billing to Plaintiffs at his home following his surgery at West Chester Hospital/UC Health and Christ Hospital.

760. The exact dates these medical bills were sent out are reflected in those medical bills.

761. These bills constituted affirmative representations by CAST that the charges related to Plaintiffs' surgery were medically appropriate and properly documented.

762. The bills were sent with the knowledge of CAST that in fact Plaintiffs' surgery was not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health and Christ Hospital associated with Dr. Durrani were not appropriate.

763. The bills sent by CAST to Plaintiffs falsely represented that Plaintiffs' surgery was appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

764. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani,

vouching for his surgical abilities, and further was appropriately billing Plaintiffs for CAST's services in association with Dr. Durrani's surgery.

765. As a direct and proximate result of this reliance on the billing of CAST, Plaintiffs incurred medical bills that she otherwise would not have incurred.

766. CAST also either concealed from Plaintiffs facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgery, or misrepresented to Plaintiffs the nature of the surgery, and the particular risks that were involved therein.

767. CAST's concealments and misrepresentations regarding Dr. Durrani, Infuse/BMP-2 or Puregen and the nature and risks of Plaintiffs' surgery were material facts.

768. Because of its superior position and professional role as a medical service provider, CAST had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

769. CAST intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgery, and thereby profited from the surgery and procedures Dr. Durrani performed on Plaintiffs at West Chester Hospital/UC Health and Christ Hospital.

770. Plaintiffs were unaware that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgery and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiffs' spine.

771. Had Plaintiffs known before Plaintiffs' surgery that Infuse/BMP-2 or Puregen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgery with Dr. Durrani at West Chester Hospital/UC Health and Christ Hospital.

772. Plaintiffs are still awaiting itemized billing from CAST reflecting the exact totals charged for the use of BMP-2 on the Plaintiffs.

773. As a direct and proximate result of the fraud against Plaintiffs by CAST, Plaintiffs sustained all damages requested in the prayer for relief.

WEST CHESTER HOSPITAL/UC HEALTH COUNTS:

COUNT I: NEGLIGENCE

774. West Chester Hospital/UC Health owed their patient, Plaintiffs, through its agents and employees the duty to exercise the degree of skill, care, and diligence an ordinarily prudent health care provider would have exercised under like or similar circumstances.

775. West Chester Hospital/UC Health acting through its agents and employees breached their duty by failing to exercise the requisite degree of skill, care and diligence that an ordinarily prudent health care provider would have exercised under same or similar circumstances through, among other things, negligent diagnosis, medical mismanagement and mistreatment of Plaintiffs, including but not limited to improper selection for surgery, improper performance of the surgery, improper assistance during Plaintiffs' surgeries and improper follow up care addressing a patient's concerns.

776. The agents and employees who deviated from the standard of care include nurses, physician assistants, residents and other hospital personnel who participated in Plaintiffs' surgeries.

777. The management, employees, nurses, technicians, agents and all staff during the scope of their employment and/or agency of West Chester Hospital/UC Health's knowledge and approval, either knew or should have known the surgery was not medically necessary based upon Dr. Durrani's known practices; the pre-op radiology; the pre-op evaluation and assessment; and the

violation of their responsibility under the bylaws, rules, regulations and policies of West Chester Hospital/UC Health.

778. As a direct and proximate result of the aforementioned negligence and deviation from the standard of care by the agents and employees of West Chester Hospital/UC Health, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

779. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiffs constitute medical negligence, lack of informed consent, battery, and fraud.

780. West Chester Hospital/UC Health negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules by:

- a. Allowing Dr. Durrani to repeatedly violate the West Chester Hospital/UC Health bylaws with its full knowledge of the same;
- b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at West Chester Hospital;
- c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by West Chester Hospital staff, doctors, Dr. Durrani's patients and by others;
- d. Ignoring information, they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including Children's Hospital, University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

781. The Safe Medical Device Act required entities such as West Chester Hospital/UC Health to report serious injuries, serious illnesses, and deaths related to failed medical devices to the

FDA and the manufacturer; this was never done.

782. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: FRAUD

783. West Chester Hospital/UC Health sent out billing to Plaintiffs at his home following his surgeries at West Chester Hospital.

784. The exact dates these medical bills were sent out are reflected in those medical bills.

785. These bills constituted affirmative representations by West Chester Hospital/UC Health that the charges related to Plaintiffs' surgeries were medically appropriate and properly documented.

786. The bills were sent with the knowledge of West Chester Hospital/UC Health that in fact Plaintiffs' surgeries were not appropriately billed and documented and that the services rendered at West Chester Hospital/UC Health associated with Dr. Durrani were not appropriate.

787. The bills sent by West Chester Hospital/UC Health to Plaintiffs falsely represented that Plaintiffs' surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

788. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiffs for West Chester Hospital/UC Health's services in association with Dr. Durrani's surgeries.

789. As a direct and proximate result of this reliance on the billing of West Chester Hospital/UC Health, Plaintiffs incurred medical bills that he otherwise would not have incurred.

790. West Chester Hospital/UC Health also either concealed from Plaintiffs facts they knew about Dr. Durrani, including that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgery, or misrepresented to Plaintiffs the nature of the surgery, and the particular risks that were involved therein.

791. West Chester Hospital/UC Health's concealments and misrepresentations regarding Infuse/BMP-2 or Puregen and the nature and risks of Plaintiffs' surgeries were material facts.

792. West Chester Hospital/ UC Health billed Plaintiffs, Louise Bayliss, for "OR ALLOGRAFTS" in the amount of \$5,441.20; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 used in Plaintiff's October 4, 2010 surgery.

793. West Chester Hospital/ UC Health billed Plaintiffs, Kevin Hartness, for "OR ALLOGRAFTS" in the amount of \$2,600.34; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 or PureGen used in Plaintiff's March 23, 2011 surgery.

794. West Chester Hospital/ UC Health billed Plaintiffs, Kevin Hartness, for "OR ALLOGRAFTS" in the amount of \$14,979.76; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's September 17, 2010 surgery.

795. West Chester Hospital/ UC Health billed Plaintiffs, Jennifer Hickey, for "OR ALLOGRAFTS" in the amount of \$9,346.51; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 or PureGen used in Plaintiff's November 5, 2010 surgery.

796. West Chester Hospital/ UC Health billed Plaintiffs, Sarah Juergens, for "OR ALLOGRAFTS" in the amount of \$18,872.73; upon information and belief, Plaintiffs believes

that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's September 15, 2010 surgery.

797. West Chester Hospital/ UC Health billed Plaintiffs, Sarah Juergens, for "OR ALLOGRAFTS" in the amount of \$14,995.80; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 or PureGen used in Plaintiff's October 27, 2010.

798. West Chester Hospital/ UC Health billed Plaintiffs, Amanda Koch, for "OR MED SURG SUPPLY" in the amount of \$2028.43; upon information and belief, Plaintiffs believes that "OR MED SURG SUPPLY" is Infuse/BMP-2 or PureGen used in Plaintiff's September 20, 2010 surgery.

799. West Chester Hospital/ UC Health billed Plaintiffs, Amanda Koch, for "OR MED SURG SUPPLY" in the amount of \$7,362.90; upon information and belief, Plaintiffs believes that "OR MED SURG SUPPLY" is Infuse/BMP-2 or PureGen used in Plaintiff's August 17, 2012 surgery.

800. West Chester Hospital/ UC Health billed Plaintiffs, Linda Kallmeyer Ward, for "OR ALLOGRAFTS" in the amount of \$5418.28; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's August 30, 2010 surgery.

801. West Chester Hospital/ UC Health billed Plaintiffs, Linda Kallmeyer Ward, for "OR ALLOGRAFTS" in the amount of \$12,392.86; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's October 4, 2010 surgery.

802. West Chester Hospital/ UC Health billed Plaintiffs, Ronald Rowley, for "OR ALLOGRAFTS" in the amount of \$12,368.70; upon information and belief, Plaintiffs believes

that "OR ALLOGRAFTS" is Infuse/BMP-2 and /or PureGen used in Plaintiff's August 25, 2010 surgery.

803. Plaintiffs, Carolyn Hursong, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

804. Plaintiffs, Katelyn Kauffman, are still awaiting itemized billing statements from West Chester Hospital/ UC Health.

805. Plaintiffs, Ruyimbo Nyemba, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

806. Plaintiffs, Billy Spivy, is still awaiting itemized billing statements from West Chester Hospital/ UC Health.

807. Because of its superior position and professional role as a medical service provider, West Chester Hospital/UC Health had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

808. West Chester Hospital/UC Health intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiffs at West Chester Hospital/UC Health.

809. Plaintiffs were unaware that Infuse/BMP-2 or Puregen would be used in Plaintiffs' surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiffs' spine.

810. Had Plaintiffs known before Plaintiffs' surgeries that Infuse/BMP-2 or Puregen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgeries with Dr. Durrani at West Chester Hospital/UC Health.

811. As a direct and proximate result of the fraud upon Plaintiffs by West Chester Hospital/UC Health, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT IV: SPOILIATION OF EVIDENCE

812. West Chester Hospital/UC Health through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

813. West Chester Hospital/UC Health through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

814. West Chester Hospital/UC Health's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

COUNT V: OHIO CONSUMER SALES PROTECTION ACT

815. Although the Ohio Consumer Sales Protection Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

816. West Chester Hospital/UC Health's services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

817. West Chester Hospital/UC Health omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

818. West Chester Hospital/UC Health's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

819. West Chester Hospital/UC Health was fully aware of its actions.

820. West Chester Hospital/UC Health was fully aware that Plaintiffs were induced by and relied upon West Chester Hospital/UC Health's representations at the time West Chester Hospital/UC Health was engaged by Plaintiffs.

821. Had Plaintiffs been aware that West Chester Hospital/UC Health's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

822. West Chester Hospital/UC Health, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

823. West Chester Hospital/UC Health's actions were not the result of any bona fide errors.

824. As a result of West Chester Hospital/UC Health's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

- a. Loss of money paid
- b. Severe aggravation and inconveniences
- c. Under O.R.C. 1345.01 Plaintiffs are entitled to:
 - i. An order requiring West Chester Hospital/UC Health restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;
 - ii. All incidental and consequential damages incurred by Plaintiffs;
 - iii. All reasonable attorneys' fees, witness fees, court costs and other fees incurred.

BILLY SPIVY vs. TCH COUNTS:

COUNT I: NEGLIGENT CREDENTIALING, SUPERVISION, & RETENTION

825. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiffs constitute medical negligence, lack of informed consent, battery, and fraud.

826. TCH negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules in numerous ways, including, but not limited to:

- a. Allowing Durrani to repeatedly violate TCH bylaws with its full knowledge of the same;
- b. failing to adequately review, look into, and otherwise investigate Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at TCH;
- c. ignoring complaints about Durrani's treatment of patients reported to it by TCH staff, doctors, patients and others;
- d. ignoring information, they knew or should have known pertaining to Durrani's other privileged time at other area hospitals.

827. The Safe Medical Device Act required entities such as TCH to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

828. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT II: SPOILIATION OF EVIDENCE

829. TCH through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

830. TCH through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

831. TCH's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

COUNT III: FRAUD

832. TCH sent out billing to Plaintiffs at his home following his surgery at TCH.

833. The exact dates these medical bills were sent out are reflected in those medical bills.

834. These bills constituted affirmative representations by TCH that the charges related to Plaintiffs' surgeries were medically appropriate and properly documented.

835. The bills were sent with the knowledge of TCH that in fact Plaintiffs' surgeries were not appropriately billed and documented and that the services rendered at TCH associated with Dr. Durrani were not appropriate.

836. The bills sent by TCH to Plaintiffs falsely represented that Plaintiffs' surgeries were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

837. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiffs for TCH's services in association with Dr. Durrani's surgeries.

838. As a direct and proximate result of this reliance on the billing of TCH, Plaintiffs incurred medical bills that he otherwise would not have incurred.

839. TCH also either concealed from Plaintiffs that they knew about Dr. Durrani, including that Infuse/BMP-2 and/or Puregen would be used in Plaintiffs' surgeries, or misrepresented to Plaintiffs the nature of the surgeries and the particular risks that were involved therein.

840. TCH's concealments and misrepresentations regarding Infuse/BMP-2 and/or Puregen and the nature and risks of Plaintiffs' surgeries were material facts.

841. TCH intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgeries, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiffs at TCH.

842. Christ Hospital billed Plaintiffs, Billy Spivy, for "OR ALLOGRAFTS" in the amount of \$12,393.00; upon information and belief, Plaintiffs believes that "OR ALLOGRAFTS" is Infuse/BMP-2 or PureGen used in Plaintiffs' February 6, 2007 surgery.

843. Plaintiffs were unaware that Infuse/BMP-2 and/or Puregen would be used in Plaintiffs' surgeries and therefore, was unaware of the health risks of Infuse/BMP-2 or Puregen's use in Plaintiffs' spine.

844. Had Plaintiffs known before Plaintiffs' surgeries that Puregen would be used in Plaintiffs' spine and informed of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgeries with Dr. Durrani at TCH.

845. Plaintiffs are still awaiting itemized billing, from TCH, reflecting the exact totals billed to Plaintiffs for the surgery performed on Plaintiffs at Christ Hospital.

846. As a direct and proximate result of the fraud upon Plaintiffs by TCH, Plaintiffs sustained all damages requested in the prayer.

COUNT IV: OHIO CONSUMER SALES PROTECTION ACT

847. Although the Ohio Consumer Sales Protection Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

848. TCH's services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A) and applicable law.

849. TCH omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

850. TCH's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

851. TCH was fully aware of its actions.

852. TCH was fully aware that Plaintiffs were induced by and relied upon West TCH's representations at the time TCH was engaged by Plaintiffs.

853. Had Plaintiffs been aware that TCH's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

854. TCH, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

855. TCH's actions were not the result of any bona fide errors.

856. As a result of TCH's unfair, deceptive and unconscionable acts and practices, Plaintiffs have suffered and continues to suffer damages, which include, but are not limited to the following:

- a. loss of money paid;
- b. severe aggravation and inconveniences;
- c. under ORC 1345.01 Plaintiffs are entitled to

- i. an order requiring TCH restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and / or actual / statutory damages for each violation;
- ii. all incidental and consequential damages incurred by Plaintiffs
- iii. all reasonable attorneys' fees, witness fees, court cost and other fees incurred.

COUNT V: PRODUCTS LIABILITY

857. At all times Infuse/BMP-2 and Puregen are and were products as defined in R.C. § 2307.71(A)(12) and applicable law.

858. TCH (aka supplier) supplied either Medtronic's (aka manufacturer) Infuse/BMP-2 for surgery performed by Dr. Durrani on Plaintiffs.

859. TCH, as a supplier, failed to maintain Infuse/BMP-2 properly.

860. TCH did not adequately supply all components required to use either Infuse/BMP-2 properly.

861. TCH knew or should have known the FDA requirements and Medtronic's requirements for using either Infuse/BMP-2.

862. TCH stored either Infuse/BMP-2 at its facility.

863. TCH ordered either Infuse/BMP-2 for surgery performed by Durrani.

864. TCH did not adequately warn Plaintiffs that Infuse/BMP-2 would be used without all FDA and manufacturer required components.

865. TCH did not gain informed consent from Plaintiffs for the use of Infuse/BMP-2, let alone warn of the supplying of the product without FDA and manufacturer requirements.

866. TCH failed to supply either Infuse/BMP-2 (aka product) in the manner in which it was represented.

867. TCH failed to provide any warning or instruction in regard to Infuse/BMP-2, and failed to make sure any other party gave such warning or instruction.

868. Plaintiffs suffered physical, financial, and emotional harm due to TCH's violation of the Ohio Products Liability act. Plaintiffs' injuries were a foreseeable risk.

869. Plaintiffs did not alter, modify or change the product, nor did Plaintiffs know that the product was being implanted without all required components.

870. TCH knew or should have known that the product was extremely dangerous and should have exercised care to provide a warning that the product was being used and that the product was being used outside FDA and manufacturer requirements. The harm caused to Plaintiffs by not providing an adequate warning was foreseeable.

871. TCH knew that the product did not conform to the representation of the intended use by the manufacturer yet permitted the product to be implanted into Plaintiffs.

872. TCH, as a supplier, acted in an unconscionable manner in failing to supply the product without all FDA and manufacturer required components.

873. TCH, as a supplier, acted in an unconscionable manner in failing to warn Plaintiffs that the product was being supplied without all FDA and manufacturer required components.

874. TCH's actions demonstrate they took advantage of the Plaintiffs inability, due to ignorance of the product, to understand the product being implanted without FDA and manufacturer required components.

875. TCH substantially benefited financially by the use of the product as the product allowed for Defendant to charge more for the surgery.

876. Plaintiffs suffered economic loss as defined in R.C. § 2303.71(A)(2) and applicable law,

877. Plaintiffs suffered mental and physical harm due to TCH's acts and omissions,

878. Plaintiffs suffered emotional distress due to acts and omissions of TCH and are entitled to recovery as defined in R.C. § 2307.71(A)(7) and applicable law.

879. TCH violated the Ohio Products Liability Act R.C. § 2307.71-2307.80

880. TCH violated R.C. § 2307.71(A)(6).

881. TCH violated The Ohio Consumer Sales Practices Act R.C. § 1345.02-.03.

882. TCH provided inadequate warnings are defined in R.C. § 2307.76(A) and applicable law.

AMANDA KOCH vs CHILDREN'S HOSPITAL COUNTS:

COUNT I: VICARIOUS LIABILITY

883. At all times relevant, Defendant Dr. Durrani was an agent, apparent agent, and/or employee of Children's Hospital.

884. Dr. Durrani is in fact, a partial owner or shareholder of Children's Hospital.

885. Defendant Dr. Durrani was performing within the scope of his agency, real or apparent with Children's Hospital during the care and treatment of Plaintiffs, Amanda Koch.

886. Defendant Children's Hospital is responsible for harm caused by acts of its agents and apparent agents for conduct that was within the scope of agency under the theory of respondeat superior.

887. Defendant Children's Hospital is vicariously liable for the acts of Defendant Dr. Durrani alleged in this Complaint including all of the counts asserted against Dr. Durrani directly.

888. As a direct and proximate result of Defendant Children's Hospital's acts and omissions, Plaintiffs sustained severe and grievous injuries, prolonged pain and suffering, emotional distress, humiliation, discomfort, loss of enjoyment of life, and loss of ability to perform usual and customary activities and incurred substantial medical expenses and treatment.

COUNT II: NEGLIGENT CREDENTIALING, SUPERVISION, AND RETENTION

889. As described in the Counts asserted directly against Dr. Durrani, the actions of Dr. Durrani with respect to Plaintiffs, Amanda Koch, constitute medical negligence, lack of informed consent, battery, and fraud.

890. Children's Hospital negligently credentialed, supervised, and retained Dr. Durrani as a credentialed physician, violating their bylaws and JCAHO rules by:

- a. Allowing Dr. Durrani to repeatedly violate the Children's Hospital bylaws with it's full knowledge of the same;
- b. Failing to adequately review, look into, and otherwise investigate Dr. Durrani's educational background, work history and peer reviews when he applied for and reapplied for privileges at Children's Hospital;
- c. Ignoring complaints about Dr. Durrani's treatment of patients reported to it by Children's Hospital staff, doctors, Dr. Durrani's patients and by others;
- d. Ignoring information they knew or should have known pertaining to Dr. Durrani's previous privileged time at other Cincinnati area hospitals, including University Hospital, Deaconess Hospital, Good Samaritan Hospital and Christ Hospital.

891. The Safe Medical Device Act required entities such as Children's Hospital to report serious injuries, serious illnesses, and deaths related to failed medical devices to the FDA and the manufacturer; this was never done.

892. As a direct and proximate result of the negligent credentialing, supervision, and retention of Dr. Durrani, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT III: FRAUD

893. Children's Hospital sent out billing to Plaintiffs at his home following his surgeries at Children's Hospital.

894. The exact dates these medical bills were sent out are reflected in those medical bills.

895. These bills constituted affirmative representations by Children's Hospital that the charges related to Plaintiffs' surgery were medically appropriate and properly documented.

896. The bills were sent with the knowledge of Children's Hospital that in fact Plaintiffs' surgery were not appropriately billed and documented and that the services rendered at Children's Hospital associated with Dr. Durrani were not appropriate.

897. The bills sent by Children's Hospital to Plaintiffs falsely represented that Plaintiffs' surgery were appropriately indicated, performed and medically necessary in contra-indication of the standard of care.

898. Plaintiffs relied on the facility holding Dr. Durrani out as a surgeon and allowing him to perform surgeries at its health care facility as assurance the facility was overseeing Dr. Durrani, vouching for his surgical abilities, and further was appropriately billing Plaintiffs for Children's Hospital's services in association with Dr. Durrani's surgeries.

899. As a direct and proximate result of this reliance on the billing of Children's Hospital, Plaintiffs incurred medical bills that they otherwise would not have incurred.

900. Children's Hospital also either concealed from Plaintiffs facts they knew about Dr. Durrani, including Children Hospital misrepresenting to Plaintiffs, Amanda Koch, the nature of the surgery and the particular risks that were involved therein.

901. Children's Hospital's concealments, misrepresentations, and the nature and risks of Plaintiffs' surgery were material facts.

902. Because of its superior position and professional role as a medical service provider, Children's Hospital had a duty to disclose these material facts to Plaintiffs and a duty to refrain from misrepresenting such material facts to Plaintiffs.

903. Children's Hospital intentionally concealed and/or misrepresented said material facts with the intent to defraud Plaintiffs in order to induce Plaintiffs to undergo the surgery, and thereby profited from the surgeries and procedures Dr. Durrani performed on Plaintiffs at Children's Hospital.

904. Had Plaintiffs known before surgery of the specific, harmful risks flowing therefrom, Plaintiffs would not have undergone the surgery with Dr. Durrani at Children's Hospital.

905. As a direct and proximate result of the fraud upon Plaintiffs by Children's Hospital, Plaintiffs sustained all damages requested in the prayer for relief.

COUNT IV: SPOILIATION OF EVIDENCE

906. Children's Hospital through its agents and employees, willfully altered, destroyed, delayed, hid, modified and/or spoiled ("spoiled") Plaintiffs' records, emails, billing records, paperwork and related evidence.

907. Children's Hospital through its agents and employees, spoiled evidence with knowledge that there was pending or probable litigation involving Plaintiffs.

908. Children's Hospital's conduct was designed to disrupt Plaintiffs' potential and/or actual case, and did in fact and proximately cause disruption, damages and harm to Plaintiffs.

COUNT V: OHIO CONSUMER SALES PRACTICES ACT

909. Although the Ohio Consumer Sales Practices Statutes O.R.C 1345.01 et seq. exempts physicians, a transaction between a hospital and a patient/consumer is not clearly exempted.

910. Children's Hospital's services rendered to Plaintiffs constitute a "consumer transaction" as defined in ORC Section 1345.01(A).

911. Children's Hospital omitted suppressed and concealed from Plaintiffs facts with the intent that Plaintiffs rely on these omissions, suppressions and concealments as set forth herein.

912. Children's Hospital's misrepresentations, and its omissions, suppressions and concealments of fact, as described above, constituted unfair, deceptive and unconscionable acts and practices in violation of O.R.C 1345.02 and 1345.03 and to Substantive Rules and case law.

913. Children's Hospital was fully aware of its actions.

914. Children's Hospital was fully aware that Plaintiffs were induced by and relied upon Children's Hospital's representations at the time Children's Hospital was engaged by Plaintiffs.

915. Had Plaintiffs been aware that Children's Hospital's representations as set forth above were untrue, Plaintiffs would not have used the services of Defendants.

916. Children's Hospital, through its agency and employees knowingly committed the unfair, deceptive and/or unconscionable acts and practices described above.

917. Children's Hospital's actions were not the result of any bona fide errors.

918. As a result of Children's Hospital's unfair, deceptive and unconscionable acts and practices, Plaintiffs has suffered and continues to suffer damages, which include, but are not limited to the following:

- d. Loss of money paid
- e. Severe aggravation and inconveniences
- f. Under O.R.C. 1345.01 Plaintiffs is entitled to:
 - iv. An order requiring Children's Hospital restore to Plaintiffs all money received from Plaintiffs plus three times actual damages and/or actual/statutory damages for each violation;
 - v. All incidental and consequential damages incurred by Plaintiffs;
 - vi. All reasonable attorneys' fees, witness fees, court costs and other fees incurred.

919. The Defendants as detailed in this entire Complaint herein engaged in a criminal enterprise through a pattern of corrupt activity and the collection of an unlawful debt.

**COUNT VI: AGAINST ALL DEFENDANTS O.R.C. 2923.32 ENGAGING IN A
PATTERN OF CORRUPT ACTIVITY; FINES; PENALTIES; FORFEITURE;
RECORDS AND REPORTS; THIRD-PARTY CLAIMS TO PROPERTY SUBJECT TO
FORFEITURE (State RICO)**

920. Plaintiffs adopt and incorporate herein by reference each and every allegation in this Complaint as detailed to support the pattern of corrupt activity including regarding BMP-2 and PureGen.

921. Pursuant to, O.R.C 2923.32 (A),

(A)(1) No person employed by, or associated with, any enterprise shall conduct or participate in, directly or indirectly, the affairs of the enterprise through a pattern of corrupt activity or the collection of an unlawful debt.

(2) No person, through a pattern of corrupt activity or the collection of an unlawful debt, shall acquire or maintain, directly or indirectly, any interest in, or control of, any enterprise or real property.

(3) No person, who knowingly has received any proceeds derived, directly or indirectly, from a pattern of corrupt activity or the collection of any unlawful debt, shall use or invest, directly or indirectly, any part of those proceeds, or any proceeds derived from the use or investment of any of those proceeds, in the acquisition of any title to, or any right, interest, or equity in, real property or in the establishment or operation of any enterprise.

A purchase of securities on the open market with intent to make an investment, without intent to control or participate in the control of the issuer, and without intent to assist another to do so is not a violation of this division, if the securities of the issuer held after the purchase by the purchaser, the members of the purchaser's immediate family, and the purchaser's or the immediate family members' accomplices in any pattern of corrupt activity or the collection of an unlawful debt do not aggregate one per cent of the outstanding securities of any one class of the issuer and do not

confer, in law or in fact, the power to elect one or more directors of the issuer.

Ohio Rev. Code Ann. § 2923.32 (West)

922. The Ohio Revised Code goes on to state that “Person,” is defined as, “(G) “Person” means any person, as defined in section 1.59 of the Revised Code, and any governmental officer, employee, or entity.” Ohio Rev. Code Ann. § 2923.31 (West)

923. West Chester Hospital, LLC (hereinafter “West Chester Hospital”), was a limited liability company authorized to transact business and perform medical services in the State of Ohio and operate under the trade name West Chester Hospital.

924. UC Health is the corporate parent, owner and operator of West Chester Hospital, LLC.

925. West Chester Hospital/ UC Health would be considered an entity and according to the Ohio Revised Code definition of a person.

926. The Ohio Revised Code also states that,

(C) “Enterprise” includes any individual, sole proprietorship, partnership, limited partnership, corporation, trust, union, government agency, or other legal entity, or any organization, association, or group of persons associated in fact although not a legal entity. “Enterprise” includes illicit as well as licit enterprises.

Ohio Rev. Code Ann. § 2923.31 (West)

927. The Center for Advanced Spine Technologies, Inc. (hereinafter “CAST”), was licensed to and did in fact perform medical services in the State of Ohio, and was and is a corporation authorized to transact business in the State of Ohio and Kentucky.

928. Dr. Durrani was the sole owner of CAST and was directly associated with CAST.

929. CAST is an enterprise.

930. West Chester Hospital/ UC Health suspended Dr. Durrani privileges on August 6, 2010.

931. Dr. Durrani continued to see new clients and/ or perform unnecessary surgeries, even though he was under suspension including those of Plaintiffs.

932. West Chester Hospital/ UC Health had knowledge that Dr. Durrani was performing surgeries while under suspension.

933. West Chester Hospital/ UC Health had knowledge that Dr. Durrani was categorizing the unnecessary surgeries as "emergencies," and West Chester Hospital/UC Health allowed the surgeries to continue. West Chester Hospital/ UC Health billed for these fraudulent surgeries and aided and conspired with CAST and Dr. Durrani to achieve these acts.

934. Dr. Durrani was on suspension for incomplete charts, medical records and late dictations of his surgeries, yet, West Chester Hospital/ UC Health allowed for Dr. Durrani to perform more unnecessary surgeries and then billed Plaintiffs for those surgeries.

935. Dr. Durrani would see Plaintiffs at his CAST offices.

936. Dr. Durrani would tell Plaintiffs that without surgery, immediately, they would suffer paralysis or death. Plaintiffs would then have the surgery.

937. CAST would schedule the surgery with West Chester Hospital/ UC Health.

938. West Chester Hospital/ UC Health would then allow Dr. Durrani to perform, the unnecessary, surgery on the Plaintiffs and West Chester Hospital/ UC Health would then bill for those unnecessary surgeries.

939. West Chester Hospital/ UC Health allowed for and participated in the fraudulent billing practices, assault due to the unnecessary surgeries, and conspired to aid CAST and Dr. Durrani in these corrupt activities.

940. West Chester Hospital/ UC Health profited from Dr. Durrani's unnecessary surgeries and

West Chester Hospital/UC Health billed Plaintiffs for the unnecessary surgeries, even though Dr. Durrani was under suspension and was not allowed to see new patients and/or perform surgeries.

941. West Chester through the fraudulent billing practices and collected unlawful debt collection, from unnecessary surgeries, had an interest in helping CAST continue to lure Plaintiffs into unnecessary surgeries and allow the unnecessary surgeries to occur, even though Dr. Durrani was under suspension. This corrupt practice started in May 2009 through at least September 2013, for the purpose of these particular Plaintiffs.

942. West Chester Hospital/ UC Health, billed Plaintiffs for the unnecessary surgeries, and used the proceeds in the operation of the enterprises.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests and seeks justice in the form and procedure of a jury, verdict and judgment against Defendants on all claims for the following damages:

1. Past medical bills;
2. Future medical bills;
3. Lost income and benefits;
4. Lost future income and benefits;
5. Loss of ability to earn income;
6. Past pain and suffering;
7. Future pain and suffering;
8. Plaintiff seeks a finding that their injuries are catastrophic under Ohio Rev. Code §2315.18;
9. All incidental costs and expenses incurred as a result of their injuries;
10. The damages to their credit as a result of their injuries;
11. Punitive damages;
12. Costs;

13. Attorneys' fees;
14. Interest;
15. All property loss;
16. All other relief to which they are entitled including O.R.C. 1345.01
17. All relief under O.R.C. 2923.32. Based upon 1-16 itemization of damages, the damages sought exceed the minimum jurisdictional amount of this Court and Plaintiff seeks in excess of \$25,000.

Respectfully Submitted,



Matthew Hammer (0092483)

Lindsay Boese (0091307)

Attorneys for Plaintiff

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Independence, KY 41051

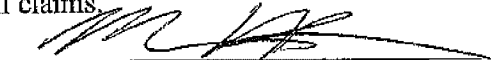
Phone: 513-729-1999

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JURY DEMAND

Plaintiffs make a demand for a jury under all claims.



Matthew Hammer (0092483)

Lindsay Boese (0091307)

AFFIDAVIT OF MERIT

**LOUISE BAYLISS
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 200 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges. I have also reviewed binders provided by the Deters Law Firm which they provided to defense counsel.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Louise Bayliss and the medical treatment of Louise Bayliss at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.

11. I have also reviewed the nursing summary prepared by legal counsel's office for Louise Bayliss. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.
12. Based upon my review, the following are the **facts** I rely upon:
 - A. Louise Bayliss was a 78 year old on the day of surgery by Dr. Durrani on 10/4/10. Louise had been very active with her grandchildren on a daily basis since being widowed several years earlier. Louise was known to work in her garden regularly. Louise had been a stay-at-home mom and was a very independent person. After being widowed, Louise continued to drive herself to stores, attend grandchildren's events and very capable of taking care of herself. She was considered to have the spunk and energy of someone about fifteen years younger than her actual age.
 - B. PMH: Recurrent deep vein thrombosis, on Coumadin therapy, PE despite Greenfield filter, HTN, Arthritis, Anemia, CVA, TIAs, C-Diff, Smoker and Bronchitis.
 - C. Surgical history includes Appendectomy and Cervical Anterior Discectomy.
 - D. 9/7/10 – Louise had consulted with Dr. Chetna Mital, PCP for generalized weakness and was found to have cervical stenosis. Louise stated to Dr. Mital that she had been falling a lot, was dizzy and unbalanced frequently. Louise apparently had a fall resulting in neck pain which was actually a thoracic fracture (T1). Dr. Mital recommended Dr. Durrani to Louise and her daughter, Sherrie. Louise tolerated this neck pain for a period of two weeks prior to consulting with Dr. Durrani. Surgery was completed on 10/4/10.
 - E. 11/16/10 – Louise had visited Dr. Mital for diarrhea, dysphagia, left shoulder pain secondary to fall, myalgia, hyperlipidemia and carotid doppler results, which are not mentioned. Louise was advised to keep her INR between 2 and 3. Dr. Mital had also recommended Louise see a Neurologist, Dr. Ossman in regards to the generalized weakness and abnormal MRI.
 - F. 3/30/11 – Louise was an inpatient at Fort Hamilton Hospital for shortness of breath, symptoms of pneumonia and continued to have right leg weakness. She was alert, attentive, appropriate and speech slightly slurred also. A Neurology

consult with Dr. Ossman was obtained. Further workup for unusual hyperreflexia was recommended. Workup for Myasthenia Gravis and antibodies were sent out. Dr. Ossman stated Louise apparently had a stroke 4/2010 and had been walker dependent since and she had white matter disease of the brain with mild atrophy.

- G. In between hospital admissions and rehab stays, Louise remained at home with the family members being attentive on a 24/7 basis. Louise's pain was consuming her life. Louise could not talk or eat food without choking which led to thick liquids. Her decreased nutrition led to her increased weakness and inability to walk. Eventually she became so weak she had to be lifted from the bed to the chair to be wheeled around. Needless to say Louise continued to lose weight from 125 lbs to 90 lbs.
- H. 6/30/11 - Louise had a Fort Hamilton Hospital ER visit for generalized weakness, a productive cough with elevated white count but no fever, an elevated creatinine 1.6, BUN 26, chronic low back pain and was admitted for community-acquired pneumonia and acute renal insufficiency. Per son, Louise had not been eating or drinking as usual. Louise was admitted for further management of this pneumonia.
- I. 8/19/11 - West Chester Hospital ER visit for coughing, dehydration/volume depletion (BUN 32 now), being more withdrawn and increased weakness and debilitation which will require nursing home placement upon discharge. Neurology consult noted Louise's speech remained slightly slurred, she was alert and attentive, failure to thrive and a change in mental status with possible cerebrovascular accident.
- J. 9/2/11 - University Hospital - Modified Barium Swallow revealed moderately severe pharyngeal dysphagia and intermittent aspiration with thin barium with delayed cough reflex.
- K. 10/5/11 - West Chester Hospital ER visit from Heritage Hill nursing home on oxygen 2L with rhonchi and wheezes particularly left base, pneumonia present per radiology finding. Its documented Louise had been a 3ppd smoker until several months ago and the cause of her severe speech disturbance is unclear. It is also noted that Louise had a right vocal cord paralysis and dysphagia probably causing the aspiration pneumonia (perhaps this is from the use of INFUSE in the cervical area, which was not approved by the FDA for the cervical area). Louise was admitted for several days and returned to the nursing home.

- L. 10/30/11 – West Chester Hospital ER visit again from the nursing home because of hemoptysis associated with low blood oxygen level. The family reporting Louise eating poorly despite their efforts with recommended pureed diet. It is documented Louise was in a depressed mood, flat affect, vocal cord paralysis, tenderness to palpation in the cervical paraspinal musculature, dysphagia, EKG – NSR with pacs’, emphysematous changes in the upper lobes, health-care acquired pneumonia, likely aspiration related and hypoxemic respiratory failure. It is stated in this ER note that the vocal cord paralysis stems from a previous cervical injury. Louise was admitted for further risk stratification management, observation, systemic antibiotic therapy with consultations to Speech Pathology, Pulmonology and Pain Management
- M. 11/1/11 – University Hospital Endoscopy Report states in the distal esophagus there was some spasm and some narrowing at the GE junction but no ulcerations. Assessment: Esophagitis with stricturing and gastritis.
- N. 11/3/11 – Swallowing Report – demonstrated aspiration with thin liquids.
- O. 12/26/11 – West Chester Hospital ER visit brought in from home by her son, Steven for decreased appetite. Steven states Louise had gotten progressively weaker during the past ten days. Steven was requesting a feeding tube because of her decreased intake. Louise often would not use the oxygen as recommended.
- P. Diagnosis: * Nursing home-acquired pneumonia with sepsis,
- severe dehydration with hypernatremia associated with acute renal insufficiency,
 - failure to thrive
 - History cerebral vascular accident with aspiration
 - Non ST-elevation myocardial infarction
- Q. Louise was admitted for PEG tube placement. On the evening of 12/27/11, Louise had an episode of pulseless electrical activity causing cardiopulmonary arrest. She underwent ACLS resuscitation with cardiac and pulmonary rhythms returning but not her mental status. Louise was admitted to the ICU with ventilator support and a very poor prognosis. The family changed her cardiac status to Do Not Resuscitate/comfort care. The family decided to take her off life support and within 30 minutes after that Louise expired on 12/28/11.
- R. Supposedly Louise had a fractured Thoracic 1, but no radiology report available to confirm.
- S. Dr. Durrani’s misinterpretations of the pre-operative diagnostic cannot determine due to the unavailability of written radiology reports.

T. Dr. Durrani performed one surgery on this client:

10/4/10 - Surgery @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Cervical spinal stenosis C5-C6, C6-C7
- Thoracic insufficiency fractured T1

PROCEDURES:

- Anterior cervical discectomy at C5-C6, C6-C7
- Anterior cervical fusion using autograft and allograft C5-C6, C6-C7
- Placement of anterior interbody cage C5-C6, C6-C7
- Anterior cervical instrumentation C5-C6, C6-C7
- Thoracic kyphoplasty T1

No Informed Consent available to confirm procedures consented.

U. INFUSE and Foam Bioact Vitoss was used during surgery.

V. The following hardware was implanted:

- 1 – INFUSE Bone graft XXS 0.7ml – Medtronic Inc Sofamor
- 1- Foam Bioact Vitoss Pack 5cc – Orthovita
- 1 – Mix Kt Bone Cem Mx Kyphx Hv-R – Kyphon Inc
- 1 – Cem Bone Hi Bln Kyphx Hv-R – Kyphon Inc
- 3 – Screw Cerv SD Uniplt 13mm T1 – Depuy Spine
- 1 – Plt Cerv Uniplt 2 Lev 40mm T1 – Depuy Spine
- 1 – Cage Cerv Bengal Std 7D 7mm – Depuy Spine
- 1 – Cage Cerv Bengal Std 7D 8mm – Depuy Spine

W. Off-Label Use: It was a Smith-Robinson approach.

X. The Operative Report was dictated by Dr. Durrani on 2/13/11 (150 days later) and verified by Dr. Durrani on 6/21/11 (270 days later).

Y. There was no failed hardware.

Z. Client has seen subsequent treating physicians in the Emergency Room on numerous occasions as noted above.

AA. According to Louise's son, Steven, she had not been out of pain since the day of surgery and on pain medication until the day she died. Louise expired on 12/28/11.

BB. Louise's son, Steven, writes adamantly that he feels the Durrani surgery (INFUSE being used in the cervical area, not FDA approved) was the initial cause of his mother's demise. Steven and his sister, Sherrie had a great deal of trust in Dr. Durrani that he knew what was best for their mother. Dr Durrani had stated she would recover quickly because he was going to do a minimally invasive procedure.

CC. Perhaps they are correct in viewing the surgery as the initial cause especially since she developed vocal cord paralysis and dysphagia which led to her weight loss and generalized weakness which progressively worsened as the months passed. The constant pain requiring pain medication which altered her mental status resulted in depression over the whole situation. Louise had stated in her ER assessment of 10/5/11 that she was asked if she wanted to die and Louise responded yes.

DD. Steven and Sherrie states that no one ever questioned Dr. Durrani's surgery being a cause of the vocal cord paralysis and the reason for the continued pain. No one ever bothered to explain to them what TIA's were and what kind of damage they can cause. Steven and Sherrie are still questioning why their mother had to experience such pain for so many months and ended up dying such a miserable death.

13. Based upon my review, the following are my opinions based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:

- A. Need to have additional surgery to repair problems created by Dr. Durrani
- B. Implantation of Puregen without informed consent
- C. Implantation of BMP-2 without informed consent
- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care

- I. Negligent surgical techniques
- J. Failure to maintain accurate and complete surgical records and surgical consent forms
- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary
- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses

- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
- GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
- HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
- II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
- JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
- KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
- LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
- MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
- NN. Failure by UC/West Chester Health to supervise staff
- OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care
- PP. Non-approved hardware combinations
- QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Louise Bayliss and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Louise Bayliss was justified in relying on the misrepresentation and did rely proximately causing harm to Louise Bayliss. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Louise Bayliss. Louise Bayliss had the right to correct information.

14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.
15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.
5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.
7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr. Durrani. This infers a poor environment of honesty and disclosure before this policy.

9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.
10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.
11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.

25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.
27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.

40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.

56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.
66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.

67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to provide oversight of Dr. Durrani as they were required to do.
70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.
78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including Dr. Shanti.

80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.
81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Louise Bayliss's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Louise Bayliss suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT



KEITH D. WILKEY M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this _____ day of March 2015.

NOTARY PUBLIC

My Commission Exp.: _____

_____ County

State of _____

**KEVIN HARTNESS
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 200 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges. I have also reviewed binders provided by the Deters Law Firm which they provided to defense counsel.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Kevin Hartness and the medical treatment of Kevin Hartness at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.

11. I have also reviewed the nursing summary prepared by legal counsel's office for Kevin Hartness. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.
12. Based upon my review, the following are the facts I rely upon:
 - A. Kevin Hartness was a 30 year old, male, divorced, father of four, (one daughter dying at three months old) on the day of Dr. Durrani first surgery on 9/17/10. Kevin's chief complaint was excruciating pain on and off affecting his neck, lower back and legs. The bilateral leg radiculopathy was burning, achy pain with pins, needles and numbness in right thigh and a stabbing pain into his groins bilaterally. Both of his legs have burning and aching on the front and posterior aspects and his toes are numb bilaterally. Kevin described the neck pain as stabbing, burning and achy sensation along with burning aching in the last three digits of his left hand and dropping things as well. Kevin rated his leg pain 6/10, middle back pain 9/10 and neck pain 8/10.

PMH: HTN, GERD, Anxiety, Depression, Kidney Failure as a young child, Hiatal Hernia and Restless Leg syndrome.
SURG HX: PE tubes
 - B. Kevin had always been active with his hunting and fishing as a young man. He was also active while raising his three children. Kevin used to work full-time for over five years for Murdock Corporation as a builder of handicapped drinking fountains. During this employment Kevin herniated two disks in lower back by lifting a fountain base in 2005.
 - C. 2007 - Kevin was involved an auto accident resulting in thoracic and lumbar fractures. Kevin says he had unsuccessful intense physical therapy, muscle relaxants, TENS unit, back brace for nine months and nerve blocks. Kevin stated his legs became weak and he did fall. Kevin did state the lumbar surgery did help him to walk again although Dr. Durrani did not inform him of the educational aspects/risks of using INFUSE during the surgery.
 - D. 7/9/10 - In a letter to Dr. Curtis B. Everson, PCP, Dr. Durrani states he had reviewed Kevin's cervical, thoracic and lumbar spine x-rays. See details below in question #2.
 - E. 7/19/10 - MRI Cervical Spine w/o Contrast @ Open MRI of Eastgate

- Findings: The C2-3, C3-4, C4-5 or C5-6 show no evidence of disc herniation or spinal stenosis and neural foramina are patent. C7-T1 and T1-2 levels are normal.
- F. The C6-C7 level shows a small right paracentral subligamentous disc herniation indenting the anterior aspect of the thecal sac. The neural foramina are patent.
(Included)
- G. 7/19/10 – MRI Lumbar Spine w/o Contrast @ Open MRI of Eastgate
Conclusion: Chronic anterior wedge compression fracture of L1
2) Broad central subligamentous L3-4 disc herniation indenting the anterior aspect of the thecal sac. 3) Small central subligamentous L3-4 disc herniation indenting the anterior aspect of the thecal sac.
- H. 7/19/10 – MRI Thoracic Spine w/o Contrast @ Open MRI of Eastgate
Conclusion: Disc desiccation, concentric bulging of the disc and a left-sided protrusion at the T8-9 level without evidence of frank extrusion at this level and other sites of thoracic disc herniation or thoracic spinal stenosis or thoracic cord compression.
- I. 7/29/10 – Kevin had an office visit with Dr. Zeeshan Tayeb, Pain Management Specialist, to be evaluated for pain control management. It was explained to Kevin regarding the Opioid Safety and Risk Assessment Protocol and he would need to sign an Opioid Agreement/Contract with the Clinic which stipulates that he engage in pain management modalities other than narcotics alone of which Kevin agreed.
- J. 8/10/10 – In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin's MRI showed a very large disk herniation at L4-L5 and L3-L4 along with significant disk degeneration and listhesis at both of these levels. Also the neck MRI showed he had a disk herniation at C6-C7.

Dr. Durrani's Impression:* Lumbar spinal stenosis associated with lumbar spondylolisthesis L3-L4 and L4-L5.

- Progressive and severe symptoms of neurogenic claudication.
- Back pain with radicular pain in both lower extremities
- Significant functional impairment
- Anterolisthesis of L3 on L4 and L4 on L5
- Central and lateral recess stenosis bilaterally at L3-L4 and L4-L5
- Failure of conservative treatment for many years.

Dr. Durrani recommended a lumbar interbody fusion at L3-L4 and L4-L5 with bilateral Foraminotomy and posterior spinal instrumentation and fusion.

- K. 8/24/10 – In a letter to Dr. Everson, Dr. Tayeb states Kevin continues to complain of aching, sharp, stabbing pain in the lower cervical spine associated with numbness and tingling in his bilateral upper extremities. He rated his pain at 10/10. Kevin and Dr. Tayeb addressed his mood disorder associated with the pain and Cymbalta was started daily.
- L. 9/2/10 - In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin was in for a repeat evaluation and preoperative discussion for his upcoming L3-L4 and L4-L5 DLIF with posterior spinal instrumentation and fusion. Kevin was scheduled for #1 surgery on 9/17/10.
- M. 9/7/10 - In a letter to Dr. Everson, Dr. Tayeb states Kevin was evaluated as a moderate risk per opioid protocol. Kevin is stable on Neurotin and Cymbalta of which he feels his mood is better and his pain control is better as well. Kevin continues to complain of pain in lower Lumbosacral spine non-radiating in nature with intermittent spasms from time to time along with lower cervical spine pain with numbness and tingling in his bilateral upper extremities. Pain rated 10/10. Kevin had an Opioid Agreement.
- N. Kevin states he told Dr. Durrani postoperatively the pain was ten times worse than it was before the lumbar surgery. Dr. Durrani tended to ignore that complaint of pain and kept focusing on the next upcoming surgery. Kevin continued to complain to Dr. Durrani regarding his neck pain.
- O. Kevin says Dr. Durrani told him if he didn't have the neck surgery, his condition would cause numbness and loss of use in his arms and eventually could end up with a seizure disorder. Kevin agreed to the second surgery being on his neck on 3/23/11.
- P. 12/2/10 – Lumbar Spine three views @ Elysium Mercy Clermont
Impression: Disc surgery from L3 through L5 without evident complication. Old mild deformity of the L1 vertebral body.
- Q. 12/15/10 - In a letter to Dr. Micheal Chunn, Dr. Durrani/Jamie Moor, PAC, states Kevin had returned for his three month post-op visit and he was doing much better but continued to have some right thigh pain of which he continued to use the helpful pain cream. He is still on Dilaudid and Percocet prn along with Valium, Neurotin, Robaxin and Colace. Kevin rated his pain 5-7/10.
- R. 12/16/10 - In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin was doing very well and he had completed physical therapy treatment.

- S. 1/13/11 - In a letter to Dr. Everson, Dr. Tayeb states Kevin was educated about the benefits of going through some cognitive behavioral therapy which is an ongoing process that takes time.
- T. 2/17/11 - In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin was in for a repeat evaluation and preoperative discussion of his upcoming one level ACDF.
- U. 4/6/11 - In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin had returned for his two week postoperative evaluation of a C6-C7 ACDF done on 3/23/11 indicating that he was very stiff and restricted in motion. Dr. Durrani states Kevin's headaches, arm and neck pain are gone but his main complaint was having some interscapular pain and stiffness with difficulty sleeping. He continues to rate his pain level fairly high.
- V. 5/6/11 - In a letter to Dr. Durrani from Frederick A. Oliver, PT, states Kevin continues to complain of significant cervical pain and restrictions in his cervical range of motion especially to the right. Kevin rating his pain 9-10/10. Percocet reduces the intensity of his pain along with turning his head or doing side bends to the right. The PT plan was to work on improving his upper body strength and tolerance to activities. The treatment should last for 8 weeks including therapeutic exercises, therapeutic activities, manual therapy techniques, neuromuscular reeducation and modalities to address Kevin's pain.
- W. 6/22/11 - Cervical Spine 2-3 Views @ Mercy Clermont
Impression: Status post cervical fusion at the C6-7 level. No acute bony abnormality or hardware complication identified. No significant degenerative change elsewhere within the cervical spine.
- X. 7/7/11 - In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin had returned for his three month post-op evaluation of a C6-C7 ACDF but he was still having neck pain. Dr. Durrani informed Kevin he would have to be under the auspices of a pain management physician in order to receive his pain medications. In the meantime, since he only completed one session of therapy he needed to go back to physical therapy for strengthening and utilize a TENS unit.
- Y. 8/16/11 - In a letter to Dr. Everson, Dr. Tayeb states Kevin had been in for an evaluation which indicated his arm pain was most consistent with damage to the cervical nerve roots and its distribution. The history and physical exam provide inconsistent findings. To resolve this issue Dr. Tayeb suggested Kevin:
- Undergo a selective nerve root block looking for concordance between anesthesia and pain relief. If the pain is completely relieved on two occasions by anesthetizing a specific dermatome, then the diagnosis is reached with 85%

certainty. A second ESI for additive effects, and a RF procedure may be indicated if the steroid proves effective but is short lived.

- Increase Percocet 5/325mg from BID to QID, R&B discussed
- Myofascial Pain – treat above first
- Mood d/o secondary to pain – cognitive behavioral therapy, increase Cymbalta to 60mg QD, R&B discussed. RTC 1 month

Z. 9/13/11 – In a letter to Dr. Everson, Dr. Tayeb states Kevin was still complaining of low back and leg pain along with neck pain radiating into his bilateral upper extremities with shooting, stabbing pains and numbness and tingling on the left side worse than the right rating it as 9/10. After discussion MS-Cotin was added along with rest, ice, heat and meditation is giving him a 25-30% relief of the pain.

AA. 9/28/11 - In a letter to Dr. Everson, Dr. Tayeb states Kevin stopped taking the MS-Contin due to the nausea it caused. Kevin says his mood has been going downhill so an SSRI was added.

BB. 10/7/11 - In a letter to Dr. Everson, Dr. Tayeb states Kevin was started on another opioid which made him so nauseous he stopped taking it and continued with the ice, heat, rest and meditation. He rated his pain 7/10.

CC. 10/21/11 - In a letter to Dr. Everson, Dr. Tayeb states Kevin continues to complain of low back and leg pain and neck and arm pain. The Duragesia Patch enabled him to sleep better and his basic control of his pain is better controlled as well.

DD. 11/18/11 - In a letter to Dr. Everson, Dr. Tayeb states Kevin's chief complaint was posterior neck, low back, right upper extremity and right lower extremity pain rating his pain 9/10 today. Kevin's long-acting opioid medication was slightly increased.

EE. 1/11/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin complains of significant amount of posterolateral pain in his right lower extremity rating his pain as 10/10. Kevin missed his L5-S1 transforaminal epidural steroid injection so it was rescheduled. There was no evidence of any aberrant drug taking behaviors.

FF. 2/8/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin continued to complain of aching, stabbing, shooting and tingling pain rating it as a 10/10. Dr. Tayeb educated Kevin regarding the TENS unit or surgery but Kevin indicated he did not want another surgical procedure. Dr. Tayeb explained that if Kevin doesn't

try anything else they would not be able to help him from a medical management standpoint. At this point Kevin was only getting about 10% relief of his pain from the opioid medication protocol.

GG. 3/14/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin is complaining of a significant amount of pain going down the anterolateral aspect of his right lower extremity for which he wants to try to do a Transforaminal epidural steroid injection. Kevin rates this pain 10/10.

HH. 3/29/12 - In a letter to Dr. Micheal Chunn, Dr. Durrani states Kevin was complaining of pain in the lower back with radicular pain going down the right lower extremity, numbness and paresthesias in the right leg.

II. 4/10/12 - MRI Lumbar Spine w/o Contrast @ Open MRI of Eastgate - Proscan

JJ. Conclusion: Postsurgical changes at the L3-4 and L4-5 levels as described. At the operated disc levels, mild narrowing of the floor of the foraminal entrance bilaterally, more prominent at L4-5 where abutment of the L4 nerve roots is also noted. 2) L5 - S1 shallow bulging disc, not compressive. 3) Chronic anterior wedge fracture of L1. (Included)

KK. 5/2/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin had just had a MRI ordered by Dr. Durrani and his pain management would remain unchanged. Kevin rated his neck, arm, back and leg pain as 10/10.

LL. 6/6/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin felt the epidural steroid injection at L4-L5 pretty much hit the spot dead on. Kevin continued to rate his pain 10/10.

MM. 10/23/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin had not been seen for several months but he was still complaining of neck, arm, low back and leg pain as aching, stabbing, shooting and tingling and rating it as 10/10.

NN. 11/15/12 - MRI Lumbar Spine w/o Contrast @ ProScan Imaging Eastgate

OO. Conclusion: Status post DLIF and posterior spine fusion L3-4 and L4-5 utilizing solitary interbody cage and posterior spine fusion without definite bridging bone identified. No compressive discopathy. No central canal stenosis, high grade foraminal stenosis or nerve root compression. 2) No compressive discopathy cephalad or caudal to the fusion.

PP. 3) When comparison is made with previous written report and images dated 4/10/12, these findings are similar.

- QQ. 11/15/12 MRI Cervical Spine w/o Contrast @ ProScan Imaging Eastgate
Conclusion: Status post anterior cervical discectomy and fusion C6-7 without definite bridging bone. No compressive discopathy. No cord compression or central canal stenosis. No foraminal Stenosis. 2) No compressive discopathy cephalad or caudal to the fusion. 3) Foraminal narrowing as detailed. 4) When comparison is made with previous written report and images dated 7/19/10, the patient has undergone the aforementioned surgery at C6-7. Foraminal narrowing is increased in conspicuity on the current examination.
- RR. 12/3/12 - In a letter to Dr. Everson, Dr. Tayeb states Kevin's diagnoses remain as cervical degenerative disk disease and cervical radiculopathy along with lumbar degenerative disk disease and lumbar radiculopathy. Prior interventional procedures gave Kevin more relief on his lumbar pain. Kevin was not currently taking any pain medication.
- SS. It was recommended that Kevin had repeat imaging study done on his cervical spine which showed postoperative changes with foraminal narrowing noted. Zanaflex and Mobic were added daily, he was to sleep in a soft collar, start on physical therapy and undergo a psyche evaluation. If Kevin has done all of this at the next visit Dr Tayeb would revisit starting him on prescriptive medicines and possibly doing future interventional injections.
- TT. 1/2/13 - In a letter to Dr. Everson, Dr. Tayeb/Bill Haney MD stated Kevin's drug screen was negative and he had been placed into our opioid protocol with no aberrant drug taking behaviors. Due to financial reasons Kevin was unable to complete the physical therapy or consider interventional procedures at this time. Dr. Tayeb felt Kevin's pain was being undertreated and he added Oxycodone 5/325 mg TID, which was one pill less than he was taking three months prior.
- UU. 1/13/13 - In a letter to Dr. Everson, Dr. Tayeb/Dr. Haney stated Kevin was currently in physical therapy and aqua therapy for his cervical and lumbar DDD, facet joint arthropathy and radiculopathy and widespread spondylosis. Kevin is 50-60% pain relief since Percocet was added to the Zanaflex and Mobic along with the therapies. He was scheduled for a cervical epidural injection. Still he had no aberrant drug taking behaviors and his scripts were refilled for another month.

VV. 2/27/13 - In a letter to Dr. Everson, Dr. Tayeb/Dr Haney stated Kevin had a good response from the cervical epidural. Currently his hips and legs are bothering him the most and considering his prescriptive report is fine, they increased Kevin's Percocet to 7.5/325mg TID for one month. Dr. Haney also ordered a TENS unit and scheduled a lumbar epidural injection.

WW. 3/27/13 -- In a letter to Dr. Everson, Dr. Tayeb/Dr Haney stated Kevin was doing pretty well currently with 40-50% subjective improvement in pain and function. Kevin's prescriptive report was fine and no evidence of aberrant drug taking behaviors. Kevin was still awaiting approval for the TENS unit.

XX. 4/26/13 -- In a letter to Dr. Everson, Dr. Tayeb/Dr Haney stated Kevin continued to have both upper and lower extremity radicular pain. The epidural injections had noticeable benefit and Kevin is doing well currently. Trazadone had been added to aid in his sleep but he continues to awaken every 2-3 hours throughout the night so he was given a prescription for Ambien 0.5 mg (15 tablets) to be used sparingly through the nights he is having extreme difficulty sleeping. A TENS unit approval is still in the process.

YY. It is debatable whether #1 and #2 surgeries were medically necessary at the time they were performed and perhaps the actual surgeries has caused the patient the amount of pain he has been in since then.

ZZ. Dr. Durrani's misinterpretation of the pre-operative diagnostic:
7/8/10 - Thoracic and Cervical Spine 2-3 Views @ Milford Medical Imaging
Impression: Cervical - Limited cervical spine with normal height and alignment from C2 through C6. Intervertebral disc spaces are unremarkable.
Impression: Thoracic - Unremarkable thoracic spine
Impression: Lumbar - Mild degenerative changes of the thoracolumbar spine with no significant change from the prior study of 11/12/08. Remote compression deformities of L1 and T12.

7/9/10 - In a letter to Dr. Curtis B. Everson, PCP, Dr. Durrani states he had reviewed Kevin's cervical, thoracic and lumbar spine x-rays. The cervical x-ray showed a discrepancy in the atlantodens interval, 1mm on one side versus 4mm on the other side along with several levels of what appears to be disk degeneration in the cervical spine. Kevin was to obtain MRIs of his cervical, thoracic and lumbar spine and return in one month.

AAA. Dr. Durrani recommended surgery on the second office visit.

BBB. Dr. Durrani performed two surgeries on this client:

#1 Surgery – 9/18/10 @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Degenerative Lumbar disk disease L3-L4 and L4-L5
- Degenerative Spinal Stenosis L3-L4 and L4-L5

PROCEDURES:

- Direct Lateral Lumbar Interbody fusion L3-L4 and L4-L5 using Autograft and Allograft
- Placement of the lateral interbody cage L3-L4 and L4-L5
- Posterior spinal instrumentation L3-L4 and L4-L5
- Posterior spinal fusion using Autograft and Allograft L3-L4 and L4-L5

The Informed Consent does not using Autograft or Allograft for L3-L4 and L4-L5.

#2 Surgery – 3/23/11 @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Degenerative cervical spinal stenosis, C5-C6 and C6-C7
- Cervical Disk Herniation C6-C7
- Cervical Spinal Stenosis C6-C7

PROCEDURES:

- Anterior Cervical discectomy C6-C7
- Anterior Cervical Fusion using Auto and Allograft, C6-C7
- Placement of anterior interbody cage C6-C7
- Placement of anterior cervical instrumentation C6-C7

The Informed Consent does not state Autograft and Allograft L3-L4 and L4-L5.

CCC. #1 and #2 Surgeries INFUSE was used.

DDD. The following hardware was implanted:

#1 Surgery - * 1 -- Foam Bioact Vitoss Pack 10cc

- 1 -- Infuse Set Bone Graft Sm – Medtronic
- 1 – 10 x 44 Capstone –L - Medtronic
- 1 – 12 x 44 Capstone – L – Medtronic
- 4 – Set Screw F/G4 Int Hex – Medtronic
- 1 – Screw Cann MA CDH 5.5 Leg 6.5 x 45 – Medtronic
- 3 – Screw Cann MA CDH 5.5 Leg 6.5 x 50 – Medtronic

- 2 – Rod Pre-Bent M8 5.5 x 75mm TI

#2 Surgery - * INFUSE Bone Graft XX SM 0.7ml – Medtronic

- 1 – Vitoss 1.2 ml – Orthovita
- 1 – Implant Zero-P 10mm Lordotic – Synthes
- 4 – 3.0 mm TI Screws - Synthes

EEE. Off-Label Use:

#1 – Surgery was a DLIF approach.

#2 – Surgery was a Smith-Robinson approach.

FFF. Operative Report Dictations:

#1 Surgery Operative Report was dictated by Dr. Atiq Durrani on 11/3/10 (47 days Later) and verified on 11/12/10 (56 days later).

#2 Surgery Operative Report was dictated by Dr. Atiq Durrani on 5/30/11 (68 days later) and verified on 6/10/11 (79 days later).

GGG. No failed hardware.

HHH. Client has seen Pain Management Specialists, Dr. Zeeshan Tayeb and Dr. Bill Haney.

III. Kevin according to documentation continues to have more pain than he had before the #1 surgery. Kevin continues to need constant opioid therapy which is well supervised.

JJJ. Kevin says after the cervical surgery he experienced needles in his neck like bone spurs and decreased range of motion and now he is not able to drive anymore. He has to sleep in his recliner, has loss of intimacy with his finance', migraines and numbness in his arms and hands. As documented by the Pain Specialists, Kevin has adhered to the Opioid Protocol and continues to need medication since the date of the first surgery. Kevin is not able to touch his toes and not able to twist his body of any kind.

KKK. According to a psychological evaluation of 12/21/12 by Dr. Micheal T. Farrell that Kevin is on Social Security Disability. He spends 70% of his day sitting in his recliner, helps with his young children and some household chores. His finance' of seven years does the driving, he no longer is able to fish or hunt or engage in recreational activities. His social life revolves around his family and attending church weekly. Kevin has not been able to work since the MVA in 2007.

13. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:
- A. Need to have additional surgery to repair problems created by Dr. Durrani
 - B. Implantation of Puregen without informed consent
 - C. Implantation of BMP-2 without informed consent
 - D. Failed hardware
 - E. Failure to obtain proper informed consent for surgery
 - F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
 - G. Failure to properly post-op monitor the patient
 - H. Failure to properly perform follow up, post-op care
 - I. Negligent surgical techniques
 - J. Failure to maintain accurate and complete surgical records and surgical consent forms
 - K. Failure to disclose important health information to patient
 - L. Failure to maintain and complete discharge summary
 - M. Failure to supervise Dr. Durrani
 - N. Negligent pre-surgical diagnosis
 - O. Failure to prepare a timely operative report or other medical record
 - P. Billing for services not completed
 - Q. Not informing the patient another surgeon will be doing all or part of the surgery
 - R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications

- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
- GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
- HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
- II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
- JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
- KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent

LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information

MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient

NN. Failure by UC/West Chester Health to supervise staff

OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care

PP. Non-approved hardware combinations

QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Kevin Hartness and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Kevin Hartness was justified in relying on the misrepresentation and did rely proximately causing harm to Kevin Hartness. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Kevin Hartness. Kevin Hartness had the right to correct information.

14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.

15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.

3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.
5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.
7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr. Durrani. This infers a poor environment of honesty and disclosure before this policy.
9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.
10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.
11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.

18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.
27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."

34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.

49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr.

Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.
66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to provide oversight of Dr. Durrani as they were required to do.
70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.

75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.
78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including Dr. Shanti.
80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.
81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Kevin Hartness's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Kevin Hartness suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life

- F. Past medical expenses
- G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
- H. Aggravation of a pre-existing condition
- I. Decreased ability to earn income
- J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT

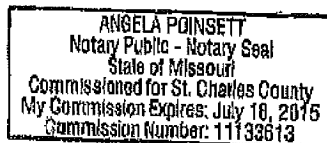



KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 4 day of ^{May}~~April~~, 2015.





NOTARY PUBLIC
My Commission Exp.: 07/18/2015
St. Charles County
State of Missouri

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**CAROLYN HURSONG
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Carolyn Hursong and the medical treatment of Carolyn Hursong at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.
11. I have also reviewed the nursing summary prepared by legal counsel's office for Carolyn Hursong. Based upon the number of cases I've reviewed pertaining to Dr.

Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

12. Based upon my review, the following are the facts I rely upon:

- A. Carolyn Hursong was a 65 year old, married, mother of four adult children and grandmother of 11 and great grandma of 9. Carolyn is now retired from full-time secretarial work and spends a couple of months in the winter in Florida. Carolyn had always been an active person even after raising four children and is quite involved with all those grandchildren. She attends the grandchildrens activities very frequently when she is in town. Carolyn even rode her bike while in Florida until she had the fall. Carolyn had tripped over a toy and fell resulting in neck pain about 6-8 months prior to seeing an orthopedist. Based on this complaint Carolyn was referred to Dr. Durrani by Dr. Emmett Roper, PCP.
- B. PMH: Paroxysmal Atrial Fibrillation/Flutter, on Coumadin therapy, Atrial Tachycardia, Chronic DOE, CHF,HDL, Cardiomyopathy, HTN, Arthritis, mild OSA, Addison's Disease, Shingles, GERDs and Breast Cancer with Chemotherapy.
- C. Surgical HX: Herniorraphy, Cholecystectomy, Cardiac Cath, Lumpectomy/breast, Elbow surgery, Left knee meniscus repair, Bowel Obstruction with Resection.
- D. Carolyn says Dr Durrani told her and her husband that "he could make her as good as new". They had a lot of faith and trust in Dr. Durrani that he knew what he was doing. Carolyn and her husband say that Dr. Durrani never told them about using any kind of cementation, placing a cage or using auto/allograft. Mr. Hursong says Dr. Durrani never really explained to them about any hardware or INFUSE until she had the second surgery and then he mentioned he had to remove the old hardware.
- E. 9/9/10 - At the time of the Dr. Durrani first office visit, Carolyn was complaining of neck pain, headaches, interscapular pain and radicular pain going down right arm and was migrating to the left as well. Per Dr. Durrani's notes Carolyn also had numbness and paresthesias in the C6 and C7 distribution. It is at this visit Dr. Durrani states he reviewed her MRI and determined she needed C5-C6, C6-C7 ACDF. See details of radiology comparison below in question #2.

- F. 10/6/10 – In a letter to Dr. Roper, Dr. Durrani states Carolyn is now S/P- C4-C5, C5-C6, C6-C7 ACDF done on 10/1/10. States her radicular pain is gone, her pain score was 3/10, does have right shoulder pain, weakness in her arms and a sore throat. Carolyn was permitted to travel to Florida within a week of surgery wearing a soft collar. Carolyn had planned to go to Florida for several weeks and return for an office visit and the Christmas holidays then return to Florida. According to Dr. Durrani's letter she was to do physical therapy while in Florida for strengthening, stretching and getting her range of motion back. Carolyn says Dr. Durrani never ordered any physical therapy for her while she was in Florida because he had told her she didn't need it. Dr. Durrani had given her a refill for the Vicodin and a Medrol dosepak. She was to return in 3 months.
- G. 12/2/10 – DX Cervical Spine 2-3 views @ Mercy Fairfield
- H. Findings: The anterior aspect of the plate is just posterior to the trachea. Its position would suggest that it may be displacing the esophagus, (question - is the patient having any dysphagia).
- I. There are metallic devices seen within the musculature of overlying the left shoulder region possibly some type of stimulation device. (included)
- J. Impression: A cervical fusion has been performed. The plate appears to be displaced. The screws have backed out of the vertebral bodies at C7, C6 and C5. With this Impression it tends to make one wonder if Dr. Durrani really looked at the film and its official result by Dr. Robert Love and if he did, why would he allow this patient to go Florida for an extended period of time and not repair the loose screws and plate before 7/11/11.
- K. 12/14/10 – In a letter to Dr. Roper, Dr. Durrani states Carolyn's headaches are all gone, overall alignment was excellent but the lower screws in the plate at C7 had backed out a little bit. She was not having any swallowing problems at that time. Carolyn was to return in May
- L. 5/19/11 – In a letter to Dr. Roper, Dr. Durrani states that Carolyn had spent several months in Florida and she was having lower neck pain on both the right

and left sides. Forward flexion of the neck and looking to the right was also painful. A CT Scan of her Cervical Spine was ordered.

- M. 5/21/11 – CT Cervical Spine @ Mercy Fairfield. Impression: The anterior fixation plate that extends from C5 to C7 appears to be displaced anteriorly, most pronounced at the inferior aspects of the fusion, at the C7 level. The screws appear to have backed out somewhat. This appearance however does not appear significantly changed when compared to the recent x-ray of 12/2/10. (included)
- N. 6/2/11 – In a letter to Dr. Roper, now 6 months since Dr. Durrani was aware the screws were loosening, Dr. Durrani states Carolyn had developed significant disk degeneration at C7-T1 which he said was below the fusion. Dr. Durrani also notes the distal screw in the plate had also come loose and was interdiscal at this point. His recommendation was to do a C6-T1 ACDF and Revision of the instrumentation from C4-T1. Carolyn was also complaining of radicular pain shooting down her left leg. An MRI of the lumbar spine was ordered. #2 Surgery was scheduled for 7/11/11.
- O. 7/11/11 – In the Operative Report Dr. Durrani states unfortunately the previous screws had become significantly loose and the plate had lost its purchase in the C7 vertebral body and appeared to have backed out. The screws at C7-T1 had migrated into the disk space between C7-T1 and was causing severe stenosis and disk degeneration.
- P. This is the hardware Dr. Durrani casually mentioned to Carolyn and her husband that he had removed during the second surgery.
- Q. 6/17/11 – MRI Lumbar Spine wo Contrast @ Mercy Fairfield. Impression: Mild developing central spinal stenosis at L4-L5 as a result of degenerative and discogenic changes present at this level. Mild degenerative discogenic reaction at L2-L3, L3-L4, and L5-S1 as described in Findings.
- R. 6/30/11 – In a letter to Dr. Roper, Dr. Durrani states the MRI of the lumbar spine showed large disk herniation at the L4-L5 level causing severe bilateral foraminal stenosis. Carolyn also has Degenerative Spondylolisthesis grade 1 at L4-5.

S. Carolyn says after the #2 surgery Dr. Durrani did order physical therapy of which she completed 25 sessions over a 14 week period. Her last visit with Dr. Durrani was on 10/11/11 and was released.

T. #1 Surgery is debatable whether it needed to be done at that time. #2 surgery was definitely needed due to the loosen screws but it took 7 months from the time of discovery in office note dated 12/14/10 until 7/11/11 before these loosened screws were repaired.

U. Dr. Durrani's misinterpretation of the pre-operative diagnostic:

7/8/10 MRI Cervical SP w/o Contrast @ Mercy Hospital Fairfield

Findings: Mild retrolisthesis of C5 on C6. Probable hemangioma – C7 vertebral body.

At C4-C5 and C7-T1 levels, there is no significant disc bulge canal stenosis or neural foraminal narrowing.

At C5-C6 level there are moderately severe discogenic hypertrophic changes which result in moderate canal stenosis. The canal is narrowed to 7mm.

Impression: Changes are seen at the C5- C6 level resulting moderate canal stenosis centrally in severe right-sided neural foraminal narrowing. (included)

9/9/10 - In a letter to Dr. Roper, Dr. Durrani states he reviewed Carolyn's MRI which showed a severe disk degeneration at C5-C6 and C6-C7. At C5-C6 she has a disk herniation causing effacement of the spinal cord and thecal sac itself and causing very significant spinal stenosis at that level. Dr. Durrani's impression of Carolyn's status was severe cervical spine stenosis C5-C6 & C6-C7, herniation as mentioned previously and bilateral and foraminal stenosis at C5-C6 and C6-C7.

V. Dr. Durrani recommend surgery on the first office visit.

W. Dr. Durrani performed two surgeries on this client:

#1 - Surgery - 10/1/10 @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Degenerative Disk disease C4-C5, C5-C6, C6-C7
- Degenerative Spinal Stenosis C4-C5, C5-C6, C6-C7

PROCEDURES:

- Anterior Cervical Discectomy C4-C5, C5-C6, C6-C7
- Anterior Cervical Fusion using Autograft and Allograft, C4-C5, C5-C6, C6-C7
- Placement of Anterior Interbody Cages, C4-C5, C5-C6, C6-C6

- Placement of Anterior Cervical instrumentation, C4-C5, C5-C6, C6-C7
- Informed Consent does not mention use of INFUSE, Auto or Allograft.*

#2 – Surgery - 7/11/11 @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Cervical Spinal Stenosis, C7-T1
- Cervical Degenerative Disk Disease, C7-T1
- Cervical Spondylosis, C7-T1
- Loose Hardware from C4 to C7

PROCEDURES:

- Removal of previous instrumentation from C4 to C7
- Anterior Cervical Discectomy C7-T1
- Anterior Cervical Fusion using Auto and Allograft, C7-T1
- Placement of Anterior Interbody Cage, C7-T1
- Anterior Cervical Instrumentation, C7-T1 (Medtronic Prestige)

Informed Consent states C7-T1 ACDF, revision instrumentation, it does not state removal of previous instrumentation C4 to C7 or the usage of INFUSE, Auto and Allograft.

X. BMP-2 was used in #1 and #2 Surgeries.

Y. The following hardware was implanted:

- #1 - * 1 – INFUSE Bone Graft X SM 1.4 ml – Medtronic Inc. Sofamor
- 1 – Foam Bioact Vitoss Pack 5cc – Orthovita
 - 3 – SPCR VERT CRNRSTN – Medtronic Inc Sofamor
 - 1 – PLT Ant Cerv Zephir 55mm T1 – Medtronic Inc Sofamor
 - 3 – Screw SD 3.5 X 13mm - Medtronic Inc Sofamor
 - 4 – Screw SD 4X13mm - Medtronic Inc Sofamor
 - 2 – PIN Prefixation Zephir - Medtronic Inc Sofamor

Operative Report indicates there were three cages placed but on the Implant Log it is not specified.

- #2 - * 1 – Vitoss 1.2ml – Orthovita
- 1 - INFUSE Bone Graft XX SM 0.7ml – Medtronic Inc Sofamor
 - 1 - Implant Standalone 16X14X7mm - Medtronic Inc Sofamor
 - 1 – Screw SD 4X15mm - Medtronic Inc Sofamor

Informed Consent does not mention Removal of instrumentation only revision or using Auto and Allograft.

Z. **Off-Label Use:** It was a Smith-Robinson approach for both #1 and #2 surgeries.

- AA. #1 Operative Report was dictated by Dr. Durrani on 2/13/11 (135 days later) and verified by Dr. Durrani on 2/14/11 (136 days later).
- BB. #2 Operative Report was dictated by Dr. Durrani on 7/11/11 and verified by Dr. Durrani on 8/5/11 (24 days later).
- CC. The following consisted of failed hardware: #1 Surgery – Operative Report #2 it is stated the screws in C7 body were completely loose and had actually migrated into the C7& T1 disk space. It also stated the screws from the C4 and C5 vertebral bodies were also removed along with the entire plate. (C6 is not mentioned).
- DD. Carolyn saw Dr. Cohen at the Mayfield Clinic in which this surgeon said ‘there was nothing else he could do for her and everything looked fine to him’.
- EE. Carolyn says her activities were less after the Dr. Durrani surgery. She feels these surgeries has affected the quality of her life and that she suffers with neck pain, limited neck mobility and headaches on a daily basis. Carolyn says her pain score 3/10 is no better than it was before the surgeries and some days its worst.
- FF. Carolyn says her headaches have never gone away. In an office note of 12/14/10 Dr. Durrani states her headaches are completely gone. In that same note, Durrani also mentions that Carolyn is not having any swallowing problems when actually she has had since then but never connected the two. Carolyn also states that she has seen an ENT doctor for her earaches which seem to be getting worst lately. The ENT physician told her the earaches were from too many neck surgeries. Carolyn says she never thought to tell him about her dysphagia with some foods like bread and meat.
- GG. Carolyn’s limitations are:
Walking – was generally not a problem but recently she’s had knee surgery and now uses a cane.
Sitting – is a problem these days because her head feels very heavy after about 30 minutes without some kind of support.
Standing – again after about 30 minutes she needs to sit down and support her head and neck.
Laying down – she is able to turn to the right and left as long as she has a neck support pillow.
Sleeping – she needs a sleep medication to get to sleep then she awakens every 3 hours due to the pain and discomfort.

Lifting limit – was not a problem before the surgery but now she is limited to less than 5 lbs and is not able to lift the grandbabies onto her lap.

Household chores – she is able to load the dishwasher briefly, not able to tolerate running the vacuum or carry any laundry baskets. She is able to fold the clothes. Grocery shopping is accomplished with the assistance of her husband and the electric cart. When grocery shopping she finds she has to turn her whole upper body to look for items because of the limited mobility of her neck.

Ability to drive – she is able but would only do so in the case of an emergency because of the lack of mobility in her neck and the traffic she would encounter. She does manage the long car trips to Florida by utilizing a neck support pillow along with many frequent stops usually about every two hours.

Flexion – of her neck is limited but Carolyn states her neck clicks most of the time upon movement. She can only bend her neck forward a little.

Self care – she experiences tingling and weakness in her arms, does manage to do her own hair, dress herself and shower alone.

HH. Carolyn states she is never without neck pain and headaches on a daily basis.

13. Based upon my review, the following are my opinions based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:

- A. Need to have additional surgery to repair problems created by Dr. Durrani
- B. Implantation of Puregen without informed consent
- C. Implantation of BMP-2 without informed consent
- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care
- I. Negligent surgical techniques
- J. Failure to maintain accurate and complete surgical records and surgical consent forms

- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary
- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation

- FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
 - GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
 - HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
 - II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
 - JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
 - KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
 - LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
 - MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
 - NN. Failure by UC/West Chester Health to supervise staff
 - OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care
 - PP. Non-approved hardware combinations
 - QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Carolyn Hursong and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Carolyn Hursong was justified in relying on the misrepresentation and did rely proximately causing harm to Carolyn Hursong. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Carolyn Hursong. Carolyn Hursong had the right to correct information.
14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.

15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.
5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.
7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr. Durrani. This infers a poor environment of honesty and disclosure before this policy.
9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.
10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.

11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.

27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.

42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.

58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.


ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.
66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.

him. However, based upon the facts here, it is obvious they failed to take action.

82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Carolyn Hursong's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Carolyn Hursong suffered damages proximately caused by them, including the following:
- A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT

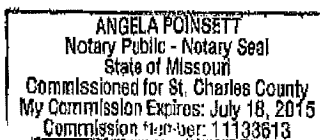


KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 5 ^{December} day of ~~November~~, 2014.





NOTARY PUBLIC
My Commission Exp.: 07/18/2015

St Charles County
State of Missouri

**SARAH JUERGENS
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 200 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges. I have also reviewed binders provided by the Deters Law Firm which they provided to defense counsel.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Sarah Juergens and the medical treatment of Sarah Juergens at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.

11. I have also reviewed the nursing summary prepared by legal counsel's office for Sarah Juergens. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.
12. Based upon my review, the following are the facts I rely upon:
 - A. Medical/social history: Sarah Juergens is a now 69 year old single Caucasian female. She was disabled prior to seeing Dr. Durrani. She denies alcohol, tobacco, or illicit drug abuse. Her prior medical history includes hypertension, coronary artery disease, arthritis, degenerative disk disease, GERD, dysthymia, tachycardia, heart murmur, renal insufficiency, incontinence, depression, abnormal EKG. Her past surgical history includes cholecystectomy '89, left nephrectomy for nonfunctional kidney '06, tonsillectomy, bilateral hip replacements '04 and '06, arrhythmia '07. Allergies to Codeine and latex.
 - B. This case involves three medically unnecessary surgeries that involve grossly negligent surgical techniques, non-consensual use of rhBMP-2 in two separate surgeries, non-approved hardware combinations, failure to maintain accurate and complete surgical records, failure to perform accurate and complete preoperative teaching, failure to maintain complete and accurate office procedure consent forms, pain and suffering due to grossly negligent surgical techniques, failure to timely assess, diagnose and treat failed hardware in second surgery, failure to continuously evaluate and reevaluate the patient for impending failed hardware post operatively. It is our stance that the Dr. Durrani and the CAST facility deviated from standards of care on multiple occurrences.
 - C. In 1987, Ms. Juergens was involved in a motor bike accident with significant vertebral disk disease and back problems. It healed initially, but then developed flare ups of pain and symptoms.
 - D. On 06/18/10, Ms. Juergens completed a C-spine MRI ordered by Dr. Durrani. The results revealed disc desiccation at C4-5 and C5-6 with bilevel disc thinning, bar-like mixed protrusion at C4-5, almost abutting the cord and broad mixed protrusion at C5-6 with moderate ventral thecal sac effacement, multilevel uncinate arthropathy with varying degrees of neural foraminal stenosis, considered severe at C4-5 and moderate at C5-6, left preforaminal disc herniation at C6-7 impressing on the exiting nerve root.
 - E. Also, on 06/18/10, Ms. Juergens completed an MRI of the L-spine ordered by Dr. Durrani. It revealed asymmetry in the sagittal and axial scanning planes, associated with probable scoliosis, multilevel disc desiccation, multilevel spinal stenosis, multifactorial at each level, neural foraminal stenosis at multiple levels.

- F. Additionally on 06/18/10, Ms. Juergens completed a scoliosis survey x-ray, as well as C-spine x-rays, ordered by Dr. Durrani. The scoliosis survey revealed an S-shaped scoliosis of the thoracolumbar spine with right convexity curvature of the lower thoracic spine centered at approximately T10, with Cobb angle of 23.5 degrees, moderate left convexity curvature of the lumbar spine centered at L3, with Cobb angle of 46.2 degrees. Degenerative disc thinning is present at multiple levels. Frontal view of the chest shows moderate cardiomegaly, alignment of the thoracic spine. The C-spine x-rays revealed alignment of the cervical vertebrae is anatomical with interspace narrowing at C4-5 and osteophytic spurring predominating at C4-5 and C5-6, anterolisthesis of C7 over T1 is measured at 7mm, and is prominently degenerative in nature, no fracture or prevertebral soft tissue swelling is evident.
- G. On 06/24/10, Ms. Juergens had an initial consultation with Dr. Durrani. In Mrs. Juergens's initial CAST paperwork, she states her reason for the visit was, "My back hurts and my left leg is numb. I have a pinched nerve in my back. I CAN'T STAND UP STRAIGHT." Mrs. Juergen also states, "Walking aggravates my pain the worst. I had lots of epidural shots that helped the pain, but not the numbness. The last one was in July 2007. I had physical therapy in 1987."
- H. Dr. Durrani states, "The x-rays show she has a 45 degree lumbar scoliosis and a 30 degree thoracic scoliosis. She has over 16cm of truncal imbalance on the sagittal view. Literally, her odontoid is far away from the sacrum. The MRI was seen today which shows severe lumbar stenosis in all of the lumbar segments with severe canal and foraminal stenosis. Most of the stenosis is foraminal, though. My recommendation is to do a two stage surgery. Stage 1 will be a direct lumbar interbody fusion from L1-2, L2-3, L3-4, L4-5. Stage 2 will involve posterior spinal instrumentation and fusion from T4 to S1 with lumbar interbody fusion at L5-S1. We will have her scheduled."
- I. On 09/07/10, Ms. Juergens attended another pre-op follow up with Dr. Durrani. Dr. Durrani and Ms. Juergens signed a blank generic informed consent form for surgical procedures. Ms. Juergens is noted to have signed her name in the area for which the surgical procedure should be written. This is a blatant violation of standards of care, and a fraudulent document.
- J. On 09/15/10 at West Chester Hospital, Mrs. Juergens had her first surgery completed by Dr. Durrani. Dr. Durrani lists procedures performed as "L2-3, L3-4, L4-5 lateral interbody fusion with insertion of an interbody cage and use of allograft and BMP." She was discharged afterwards to a skilled nursing facility for a few weeks, due to mobility issues.
- K. On 10/14/10, Ms. Juergens attended another pre-op follow up with Dr. Durrani. Dr. Durrani and Ms. Juergens signed a blank generic informed consent form for surgical procedures. Ms. Juergens is noted to have signed her name in the area

for which the surgical procedure should be written. This is a blatant violation of standards of care, and a fraudulent document.

- L. On 10/27/10 at West Chester Hospital, Ms. Juergens had her second surgery completed by Dr. Durrani. Dr. Durrani lists procedures performed as "Stage 2 scoliosis correction, T10-S1 posterior instrumented spinal fusion, L5-S1 axial lumbar interbody fusion, insertion of interbody cage, L5-S1, Allograft, local autograft, and BMP use." Within hours of surgery, Ms. Juergens was sent to ICU, due to findings of postoperative paroxysmal supraventricular tachycardia. A post-op nurse documented at 19:10, "Patient assessment changing. Pt had multiple episodes of SVT vs Sinus Tach. Hematoma noted upper back, more blood noted on dressing."
- M. On 10/29/10, a shift nurse documented, "Patient c/o pain 8/10 in LLE and back pain. Says leg pain shoots down outside of leg all the way to her ankle. She screams and cries after movement of any kind. Gait is unsteady and hunched, and she seems to drag LLE and left foot turns slightly outward."
- N. On 10/29/10, the occupational therapist documented during her session, "Very tearful about pain, and fearful voicing that something isn't right. Continues to have a lot of left lower extremity pain and voices that she thinks she has a blood clot. Unable to even bear weight on right lower extremity due to pain on left. Unable to stand erect."
- O. On 10/30/10, the occupational therapist documented during her session, "Voicing that her left leg and back are killing her. Unable to bear full weight though left lower extremity. Patient moaning and screaming in pain."
- P. On 10/30/10, a floor nurse documented, "Patient c/o leg pain. Patient feels like leg cramping on her even when she is sitting still. She often screams in pain."
- Q. On 10/31/10, the occupational therapist documented during her session, "Voicing that her left leg is killing her and crying out."
- R. Also on 10/31/10, an L-spine CT was obtained. It revealed, "The left sided pedicle screw at L5 does not extend into the vertebral body. The tip is in the junction of the pedicle with the vertebral body. The L3 pedicle screw on the left and on the right appears well positioned. The pedicle screw on the right at L2 courses along the lateral wall of the pedicle and lateral aspect of the vertebral body. The tip of the screw appears to extend beyond the cortex. The T12 screw of the left only extends slightly into the reterar body. The pedicle screw of the right extends well into the vertebral body. The T10 pedicle appears well positioned. Discectomies are identified at L2-L3, L3-4, and L4-5."

- S. On 11/4/10, the occupational therapist documented during her session, "Very painful and very tearful. Told me that the pain scares her. Pain is severe, hunched and unable to achieve full upright posture."
- T. On 11/03/10 at West Chester Hospital, Ms. Juergens has her third surgery completed by Dr. Durrani. Dr. Durrani lists procedures performed as "Revision and reinsertion of L2, L3, L5, and S1 pedicle screws on the left".
- U. On 11/15/10, Mrs. Juergens attended her first post-op follow up with Dr. Durrani. Dr. Durrani released her from skilled living care to home, and to continue physical and occupational therapy. He also ordered a scoliosis x-ray.
- V. On 02/11/11, Mrs. Juergens completed her scoliosis x-ray, which revealed mild thoracolumbar scoliosis.
- W. On 02/15/11, Mrs. Juergens attended a post-op follow up with Dr. Durrani. Dr. Durrani states, "Attempts to make her stand straight were met with resistance. She fell on January 10th, and since then she has noticed a decline in her function. She at this point is having a hard time standing up straight. She is standing in a forward flexed, leaning posture. X-rays seen today show overall alignment in the frontal plane is good. Sagittal plane, she is leaning significantly forward but all screws and hardware look to be intact at this point. My recommendation is to start aquatic therapy. I really want her to push herself in therapy."
- X. On 03/31/11, Mrs. Juergens attended a post-op follow up appointment with Dr. Durrani. He recommended for her to start back in physical therapy, and to use a cane at home.
- Y. On 03/01/12, Mrs. Juergens attended her one year follow up appointment with Dr. Durrani. Dr. Durrani states, "Was doing well until Christmas when she fell, and has had pain shooting around her rib cage. She describes a radicular pain in the T12 distribution. My recommendation is for her to get a CT scan of the thoracic and lumbar spine with sagittal reconstruction. My feeling is that she is having a T11-12 radiculopathy on the right side."
- Z. On 03/19/12, Mrs. Juergens completed both CT scans. The L-Spine CT revealed no evidence of acute bony abnormality or evidence of pedicular screw or posterior rod disruption. The T-Spine CT revealed no new orthopedic issues.
- AA. On 03/29/12, Mrs. Juergens attended her follow up appointment with Dr. Durrani, whom agreed with the radiology reading. He recommended a foraminal injection on the right side at the T9-10, T10-11, T11-12 distribution, pain cream, and medication for suspected "sensory neuropathy in the T11, T10 distribution".
- BB. Dr. Durrani's diagnoses correlated with said radiology.

CC. Dr. Durrani recommended a two stage surgery at Mrs. Juergen's initial office visit on 06/24/10.

DD. Dr. Durrani performed three surgeries on this client.

EE. The following hardware was implanted:

Surgery #1 (09/15/10)

Medtronic Infuse set Bone Graft MD into l-spine

One Orthovita Foam Bioact Vitoss Pack 10cc into l-spine

Two Medtronic Clydesdale 10 x 45mm into l-spine

One Medtronic Clydesdale 8 x 45mm into l-spine

Surgery #2 (10/27/10)

One Medtronic Infuse Set Bone Graft SM into l-spine

One Orthovita Vitoss 10cc into l-spine

One Trans1 Rod Spine 3D AX 9 x 12 x 45mm into l-spine

One Trans1 AxiaLif Universal Plug into l-spine

One Trans1 Axialif Stabilization System into l-spine

Twelve Depuy Spine 6.0 x 45 Viper Screw into thoracic/lumbar spine

Two Depuy Spine viper rod 300mm into thoracic/lumbar spine

Twelve Depuy Spine Set SCR SGL Innr Mechanism TI into thoracic/lumbar

spine

Surgery #3 (11/03/10)

Three Depuy Spine SCR PA CANN Viper 7 x 50mm TI into lumbar spine

One Depuy Spine SCR PA CANN Viper 7.5 x 50mm TI into lumbar spine

Four Depuy Spine Set SCR SGL Innr Mechanism TI into lumbar spine

FF. Information from Dr. Durrani's OR report indicates that rhBMP-2 was used during the first two of Ms. Juergen's three surgeries. According to the PMA submitted by Medtronic to the FDA, Infuse was intended for a single level anterior lumbar interbody fusion single performed with all three components in a specific SPINAL region. The three components that the Infuse device consists of are 1.) A metallic spinal fusion cage (the LT-Cage), 2.) The bone graft substitute, which consists of liquid rhBMP-2, and 3.) A spongy carrier or scaffold for the protein that resides in the fusion cage. With the exception of two non-spinal uses not relevant here, the FDA has not approved any other use of Infuse, including the insertion of BMP into Ms. Juergen's thoracic spine, multiple lumbar levels, and unapproved hardware combinations by Dr. Durrani. Dr. Durrani implemented BMP into a level of the non FDA approved thoracic spine, as well as multiple levels of the lumbar spine. The use of rhBMP-2 without the expressed or written consent and/or knowledge of Ms. Juergens in both surgeries is a violation of standards of care, as well as a violation of the manner in which BMP could be used, in accordance with the FDA.

GG. Operative Report Dictations:

Surgery #1 (09/15/10)

Dictated on 09/16/10

**Dr. Durrani is listed as the primary surgeon, and was in the OR for over two hours, yet Dr. Shanti did the dictation for Dr. Durrani.

Surgery #2 (10/27/10)

Dictated on 10/28/10

** Dr. Durrani is listed as the primary surgeon, and was in the OR for over two hours, yet Dr. Shanti did the dictation for Dr. Durrani.

Surgery #3 (11/03/10)

Dictated on 11/04/10

** Dr. Shanti is listed as the primary surgeon, and was in the OR for nearly two hours, while Dr. Durrani was listed as being in the OR for only 23 minutes.

HH. Ms. Juergens is to be followed by Dr. Tobler at the Mayfield Clinic.

II. The following consisted of failed hardware: After her second surgery on 10/25/10, she had to go back to surgery on 11/03/10 because of severe pain and left leg radiculopathy. Dr. Shanti states in his 11/03/10 OR dictation, "A CAT scan of the L-spine was obtained. There is evidence that the S1, the L5 and L3 pedicle screws were migrating dorsally and L5 pedicle screw was irritating, has migrated dorsally to the point that it was actually entering the foramen and causing radicular impingement. The S1 screw and L5 screw were visualized and they were clearly loose. The set screws were then removed and in a proximal extension there was clear evidence of the L3 and L2 pedicle screws were also somewhat dorsally migrated. At that point, we removed the set screws for the L2 and L3 pedicle screws as well."

JJ. Mrs. Juergens feels Dr. Durrani violated her trust by using BMP without her consent and knowledge. She is in constant pain.

13. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:

A. Need to have additional surgery to repair problems created by Dr. Durrani

B. Implantation of Puregen without informed consent

C. Implantation of BMP-2 without informed consent

- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care
- I. Negligent surgical techniques
- J. Failure to maintain accurate and complete surgical records and surgical consent forms
- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary
- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis

- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
- GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
- HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
- II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
- JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
- KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
- LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
- MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
- NN. Failure by UC/West Chester Health to supervise staff
- OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care
- PP. Non-approved hardware combinations

QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Sarah Juergens and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Sarah Juergens was justified in relying on the misrepresentation and did rely proximately causing harm to Sarah Juergens. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Sarah Juergens. Sarah Juergens had the right to correct information.

14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.
15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.
5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.

7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr. Durrani. This infers a poor environment of honesty and disclosure before this policy.
9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.
10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.
11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.

22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.
27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)

37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.

53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

ADDITIONAL OPINIONS

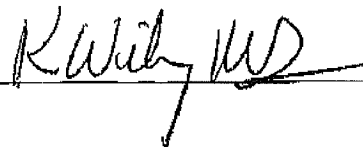
65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform

unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.

66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to provide oversight of Dr. Durrani as they were required to do.
70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.

78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including Dr. Shanti.
80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.
81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Sarah Juergens's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Sarah Juergens suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT



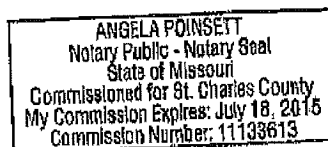
KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 16 day of ^{July}~~June~~, 2015.

Angela Poinsett
NOTARY PUBLIC
My Commission Exp.: 07/18/2015



St. Charles County
State of Missouri

Sep 27 2013 2:11PM HP LASERJET FAX

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CV13-072077

Affidavit of Merit

I, Andrew Collier, M.D., after being duly sworn and cautioned state as follows:

1. I have reviewed all relevant medical records reasonably available about Linda Kallmeyer-Ward concerning the allegations of medical negligence.
2. I am familiar with the applicable standard of care.
3. Based upon my review of this record, my education, my training, and experience, it is my belief, to a reasonable degree of medical probability that the care provided by the Defendants Dr. Durrani, CAST, West Chester Hospital and UC Health was negligent and this negligence caused injury to Linda Kallmeyer-Ward *alia*, negligent surgery; negligent surgical techniques; failure to maintain accurate and complete surgical records; negligent selection and implantation of hardware; failure to obtain proper informed consent to use, and the use of unapproved allograft/hardware combination; failure to obtain proper informed consent to use, and the use of BMP-2 in the cervical spine; failure to obtain proper informed consent to use, and the use of BMP-2 without the metal LT Cage; failure to obtain proper informed consent to use, and the use of BMP-2 in multiple levels during the same surgery; failure to obtain proper informed consent to use, and the use of BMP-2 in the same patient on more than one occasion; lax and substandard recordkeeping; failure to supervise Dr. Durrani; negligent pre and post-surgical diagnosis; improper documentation; health care fraud; battery; negligent treatment; negligent surgery; and medical negligence.
4. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or to its instruction in an accredited school.
5. My curriculum vitae is attached.

FURTHER AFFIANT SAYETH NAUGHT.

STATE OF

Pennsylvania

COUNTY OF

Philadelphia

Andrew Collier, M.D.

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED, before me, a Notary

Public, by Andrew Collier, M.D. on the 27th day of SEP., 2013.Janae Loria

Notary Public

My Comm. Exp

Sep. 23, 2016

May. 9. 2014 10:11AM OA Admin

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**KATELYN KAUFFMAN
AFFIDAVIT OF MERIT
WEST CHESTER HOSPITAL**

I, Kelth D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges,
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Katelyn Kauffman and the medical treatment of Katelyn Kauffman at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.
11. I have also reviewed the nursing summary prepared by legal counsel's office for Katelyn Kauffman. Based upon the number of cases I've reviewed pertaining to Dr.

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Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific

information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

12. Based upon my review, the following are the facts I rely upon:

- A. On 11/26/2010 Katelyn Kauffman had an MRI of the Lumbar Spine.
- B. At L5-S1, small right paracentral disc protrusion, contacting the right traversing S1 nerve root.
- C. A 3.9 cm mas at right adnexa likely represents a follicular cyst. Recommend clinical correlation, and ultrasound exam performed in 2-3 menstrual cycles to confirm resolution, as clinically indicated.
- D. It is stated in the operative report that she has failed conservative measures and decided to proceed with surgery. Miss Kauffman proceeded with the procedure based upon Dr. Durrani's clinical judgment that she would eventually become disabled.
- E. Conservative measure were not exhausted, thus making this procedure not medically necessary.
- F. Miss Kauffman had a proper interpretation of the Preoperative diagnosis. Confirmed by MRI performed on 06/25/2010.
- G. During the first office visit patient was told that she needed surgery. Dr. Durrani attempted to schedule the procedure for the following day, but was unable due to his schedule being booked. Per Dr. Durrani the surgery was urgent, as his medical opinion suggested that she would have permanent nerve damage that could eventually cause her to become unable to walk with her right leg.
- H. One procedure was performed: On 9/22/2010 the following surgery was performed: Right Sided Lumbar 5- Sacral1 Endoscopic Discectomy. This procedure was converted to an open procedure after failed attempts to dock the ports onto the L5-S1 disc.
- I. Note: Dr. Durrani did not perform this surgical procedure. The operative dictation report is signed by Dr. Nael Shanti M.D. on 11/10/2010.
- J. BMP-2 was not used during the surgery.

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- K. No hardware was implanted.
 - L. The operative report was dictated on 09/23/2010.
 - M. There was no failed hardware.
 - N. The patient has not seen a subsequent treating doctor.
 - O. As a result of the procedure performed, Miss Kauffman has returned as a patient to Cincinnati Pain Management. Miss Kauffman was told without this procedure she would eventually become disabled. As a 21 year old patient Miss Kauffman placed her trust upon Dr. Durrani to return her to normal state of life without back pain.
 - P. She continues to experience pain.
13. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:
- A. Unnecessary surgery(s). Number of surgeries 1, Number unnecessary 1
 - B. Need to have additional surgery to repair problems created by Dr. Durrani
 - C. Implantation of Puregen without informed consent
 - D. Implantation of BMP-2 without informed consent
 - E. Failed hardware
 - F. Failure to obtain proper informed consent for surgery
 - G. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
 - H. Failure to properly post-op monitor the patient
 - I. Failure to properly perform follow up, post-op care
 - J. Negligent surgical techniques
 - K. Failure to maintain accurate and complete surgical records and surgical consent forms

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- L. Failure to disclose important health information to patient
- M. Failure to maintain and complete discharge summary
- N. Failure to supervise Dr. Durrani
- O. Negligent pre-surgical diagnosis
- P. Failure to prepare a timely operative report or other medical record
- Q. Billing for services not completed
- R. Not informing the patient another surgeon will be doing all or part of the surgery
- S. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- T. Deviation in standard of care
- U. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- V. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- W. Failure by CAST to disclose additional/changed procedure and reason to patient
- X. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- Y. Prior knowledge of possible complication and not acting properly upon same
- Z. Failure to disclose pertinent health information to another health care provider
- AA. Fraudulent, negligent and reckless pre-operative work up
- BB. Fraudulent, negligent and reckless surgery
- CC. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- DD. Failure to properly educate patient regarding diagnoses
- EE. Failure to attempt non-surgical conservative treatment
- FF. Failure to perform thorough and accurate pre-op nonsurgical evaluation

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- GG. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
 - HH. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
 - II. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
 - JJ. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
 - KK. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
 - LL. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
 - MM. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
 - NN. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
 - OO. Failure by UC/West Chester Health to supervise staff
 - PP. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care
 - QQ. Non-approved hardware combinations
 - RR. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Katelyn Kauffman and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Katelyn Kauffman was justified in relying on the misrepresentation and did rely proximately causing harm to Katelyn Kauffman. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Katelyn Kauffman. Katelyn Kauffman had the right to correct information.
14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.
15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the

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following opinions relating to WCMC and UC Health pertaining to the claims against them, WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

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2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
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11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.

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27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.

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43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.

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59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.
66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to

provide oversight of Dr. Durrani as they were required to do.

70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.
78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including Dr. Shanti.
80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.
81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.

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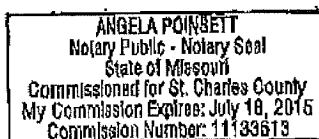
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Katelyn Kauffman's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Katelyn Kauffman suffered damages proximately caused by them, including the following:
- A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$ _____
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

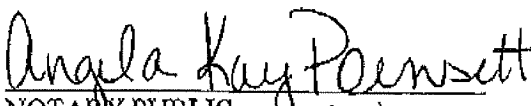
AFFIANT SAYETH FURTHER NOT


 KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D, on this 9 day of May, 2014.


 NOTARY PUBLIC
 My Commission Exp.: 07/18/2015
St. Louis County

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State of Missouri

IN THE COURT OF COMMON PLEAS
BUTLER COUNTY, OHIO
CIVIL DIVISION

FILED BUTLER CO.
COURT OF COMMON PLEAS
AUG 18 2014
MARY L. SWAIN
CLERK OF COURTS

AMANDA KOCH

Case No. CV 2013 07 2100

Plaintiffs,

JUDGE GUCKENBERGER

v.

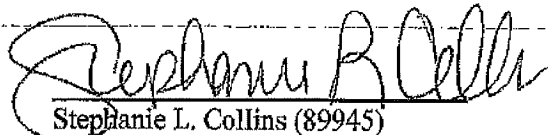
ABUBAKAR ATIQ DURRANI, M.D.,
et al.

Defendants.

NOTICE OF FILING
AFFIDAVIT OF MERIT

Now comes the Plaintiff, pursuant to CR 10(D)(2), and respectfully submits the attached Affidavit of Merits of Keith D. Wilkey, M.D. in support of Plaintiff's Complaint against all Defendants.

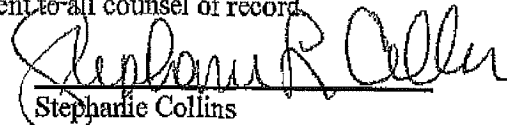
Respectfully submitted,



Stephanie L. Collins (89945)
5247 Madison Pike
Independence, KY 41051
Ph: (859) 363-1900
Fa: (859) 363-1444
scollins@ericdeters.com
Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this Notice was filed with the Butler County Clerk of Courts on August 18 2014 and an electronic copy was sent to all counsel of record.



Stephanie Collins

**AMANDA KOCH'S
AFFIDAVIT OF MERIT
FOR CHILDREN'S**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for Cincinnati Children's Hospital.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Amanda Koch and the medical treatment of Amanda Koch at Children's.
9. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.
10. I have also reviewed the nursing summary prepared by legal counsel's office for Amanda Koch. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific

information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

11. Based upon my review, the following are the facts I rely upon:

- A. Medical/social history: Amanda Koch is a now unemployed 20 year old single mother with two children. Ms. Koch denies alcohol or illicit drug abuse, but admits to ½ to 1 pack per day tobacco abuse. Her prior medical history includes anemia, urinary tract infections, asthma, kidney stones, childbirth x 2, and miscarriage x 1. Her past psychiatric history includes Obsessive-Compulsive Disorder, Bipolar Disorder. Prior surgical history includes D&C '10, cholecystectomy.
- B. This case involves three medically unnecessary surgeries that include grossly negligent surgical techniques, failure to maintain accurate and complete surgical records, failure to perform accurate and complete preoperative teaching, Failure to produce signed hospital surgical consents for two surgeries, failure to maintain complete and accurate surgical consent forms, fraudulent, negligent and reckless pre operative work up, inaccurate, fraudulent, and/or exaggeration of diagnoses, failure to properly educate patient regarding diagnoses, failure to properly educate patient regarding postoperative restrictions, intentional infliction of emotional distress due to inaccurate diagnoses and embellished medical statements, failure to maintain an accurate and complete medical record. It is our stance that the Dr. Durrani deviated from standards of care on multiple occurrences.
- C. On 11/13/07, Ms. Koch completed scoliosis x-rays, ordered by Dr. Byad Alhaj. The x-rays revealed normal two views of the spine.
- D. On 11/13/07, Ms. Koch attended an initial consultation with Dr. Durrani. Dr. Durrani dictates, "Since September, this 14 year old is having progressively increasing back pain, which shoots all the way down to her left leg into her left toes, especially the lower part of the middle toe. This is significantly getting worse. She has been in physical therapy, has done physical therapy for many months, and unfortunately continues to be very symptomatic. The MRI was reviewed today, which was from October, which essentially does not show a significant amount of disc herniation. Clinically, she has all of the signs of an L5-S1 disk herniation, which I believe must have taken place after the MRI was taken about two months ago. Repeat L-Spine MRI."
- E. Of note, Ms. Koch and her mother agree that her back pain began in September '07. Dr. Durrani states she has been in physical therapy for "many months", yet her pain began in September and he was seeing her in November. At the most, she could have had approximately eight weeks of therapy. There is no documentation of her length, compliance, and effectiveness of previous therapy. Paperwork filled out by Ms. Koch and family at the initial visit with Dr. Durrani does not reflect previous therapy. Dr. Durrani refers to an October MRI, but no copy of this MRI is disclosed. Ms. Koch has had all radiology completed at Children's Hospital, and an October 2007 MRI was not located.
- F. On 11/14/07, Ms. Koch completed L-Spine and T-Spine MRIs, ordered by Dr. Durrani. The x-rays revealed a normal noncontrast MRI of the thoracic and lumbar spine.

- G. On 11/15/07, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictates, "She reports radiating low back pain since summer of 2007. This pain has progressed in nature, and the pain has been resistant to medication and physical therapy. The pain has progressed and now occurs constantly in the back and intermittently down the left leg into the toes. Patient describes this pain as a burning sensation in nature. An MRI was reviewed and showed a left foraminal disk herniation compressing the adjacent nerve root. Proceed with a selective nerve block of the left L5-S1 neural foramina, with the attempt that this may alleviate her pain. If she continues to have pain after the epidural steroid injection she will call our office for further evaluation, possible surgical intervention."
- H. Of note, Dr. Durrani's interpretations of MRIs he ordered in November are vastly different than the radiologist. Dr. Durrani moved up the beginning of her pain to summer of 2007, rather than September 2007 that Ms. Koch reported. Dr. Durrani states that medication and physical therapy have been ineffective. The only medications reported by Ms. Koch and family for pain control were over the counter analgesics. As previously discussed, the therapy regimen also needed further clarification before deeming ineffective.
- I. On 11/27/07, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictates, "She was initially seen approximately two weeks ago for the persistent radiculopathy, and was referred to the Christ Hospital for a steroid injection at the L4-5 facet. The patient underwent the injection, however, this failed to improve her symptoms. She returns today with the persistent pain down the left leg, and describes a weakness over the lower extremity. An MRI was reviewed and showed an L4-5 left foraminal disc herniation compressing the adjacent nerve root. The family wishes to proceed with microdiscectomy on the left at L4-5. We believe this surgery will help her since she has failed other conservative treatment attempts, and the pain has progressed, and now interferes with her everyday living where she is no longer able to ambulate."
- J. On 12/06/07, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani states, "An MRI was once again reviewed from October, and does show a left L4-5 foraminal disk herniation impinging on the nerve root exiting this region. We believe that her symptoms are the result of this disk herniation seen on the left at L4-5. Because her pain has progressed and she failed conservative treatment, which included narcotic medication and spinal injections, the family would wish to proceed with a left L4-5 percutaneous microdiscectomy."
- K. Of note, Dr. Durrani is referencing an unknown MRI from October, which he himself stated at the initial visit did not show a significant amount of disc herniation. Dr. Durrani failed to reference the November L-Spine and T-Spine MRIs he ordered, which were all normal. Dr. Durrani references failed narcotic medication and spinal injection therapies. Dr. Durrani did not dictate any starting orders of narcotic medication in his notes, and she was given only one spinal injection. There is not enough documentation of aggressive conservative treatments to warrant surgical intervention, besides the obvious radiology results.
- L. On 12/10/07, at Cincinnati Children's Hospital, Ms. Koch had surgery completed by Dr. Durrani. The signed hospital surgical consent listed the procedures to be performed as "Lumbar Spine Four and Five Microdiscectomy, Spinal Monitoring". Dr. Durrani lists

procedures performed as "L4-5 foraminal discectomy". The OR dictation was dictated on 12/22/07.

- M. Ms. Koch states, "When I came into the hospital, I couldn't really walk, and I was in so much pain. After he performed the surgery, the pain was and is unbearable."
- N. On 12/10/07, Ms. Koch completed postoperative L-Spine x-rays, ordered by Dr. Steven Gammon. The x-rays revealed on the frontal radiograph, there does appear to be minimal widening of the L4-5 disc space. However, this appears normal on the lateral study. Soft tissue defect is seen overlying the L5 region. No acute radiographic abnormality of the L-spine status post L4-5 microdiscectomy.
- O. On 01/24/08, Ms. Koch attended a postop visit with Lance Bolin, PA-C to Dr. Durrani. Mr. Bolin dictates, "She was noted recently to have fallen while playing around with some friends, hitting her back on a bedpost, and having some pain issues with this. She states that she is getting better, but just making sure that nothing was too involved since she just had surgery. She denies any numbness or tingling in her lower extremities. Does not appear to be in any kind of acute distress today. Exam of her back shows it to just have a very mild swelling at the superior portion of the incision. X-rays were not done today. I feel she is getting better from just a contusion to her back. Continue therapy, rest, and ice. I have talked to Robin in physical therapy, and had them do a little extra E-Stim or ultrasound to help with some of the swelling." It is to be noted that Dr. Durrani did not sign off on this note.
- P. On 03/25/08, Ms. Koch completed L-spine x-rays, ordered by Dr. Durrani. The x-rays revealed impression alignment remains normal.
- Q. On 03/25/08, Ms. Koch attended a four month postop visit with Dr. Durrani. Dr. Durrani states, "She is doing very well, and denying any pain whatsoever. She followed the course of physical therapy, which can be stopped now. She asks for a home TENS unit, and we will give her a prescription for that. Re-schedule at one yr post op mark."
- R. Of note, Dr. Durrani states above that Ms. Koch was compliant for her physical therapy treatment, and could cease physical therapy visits.
- S. In approximately June 2009, Ms. Koch became pregnant.
- T. In March 2009, Ms. Koch gave birth to her first child.
- U. On 06/16/09, Ms. Koch attended a one year follow up visit with Dr. Durrani. Dr. Durrani dictates, "She was doing well until she had a delivery, a pregnancy. Pregnancy and delivery aggravated back pain, and made it worse. Infant is three months old, and no improvement in back pain. She has pain in the lower back that radiates down to her right leg, all the way down to her toes. Her leg has been giving out on her recently, and this is causing a significant amount of issues. She has leg numbness and pain. This is all predominantly in the left leg. She has had previous epidurals, pain medications, and physical therapy, with no relief. The x-rays show decreased disk height at both L4-5 and L5-S1 disk space. Will order MRI."
- V. Of note, Dr. Durrani again references epidurals, pain medications, and physical therapy as ineffective. Physical therapy proved to be effective after Ms. Koch's surgery

according to Dr. Durrani's own dictation on 03/25/08. There is still no available documentation regarding pain medications used in Dr. Durrani's dictations. Also, only one epidural injection had been tried at that point.

- W. On 07/01/09, Ms. Koch completed an L-Spine MRI, ordered by Dr. Durrani. The MRI revealed postoperative defect new since the prior study. Fat signal intensity fills the majority of the defect. Deep to the laminectomy defect, the left L5 nerve root is mildly enlarged. There is subtle hyperintense T2 signal in the lower dorsal aspect of the L4-5 disk, which may represent an annular tear or be related to the prior surgery. Question age related indeterminate L4-5 annular tear versus changes related to prior microdiscectomy.
- X. On 07/01/09, Ms. Koch completed a C-Spine MRI, ordered by Dr. Durrani. The MRI revealed a normal exam.
- Y. On 07/07/09, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictated, "C-Spine MRI shows a mild disk herniation at C3-4. The L-Spine MRI shows excellent results. Most of the disk still remains hydrated at L4-5, despite having a microdiscectomy done. I think overall she is doing great. Her symptoms are significantly resolved. One year follow up to be scheduled."
- Z. Of note, Dr. Durrani's interpretation of the L-Spine and C-Spine are markedly contrasted to the radiology read.
- AA. On 04/08/10, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani states, "Her insurance unfortunately denied the MRI, so we started her on physical therapy and I will see her back in six weeks."
- BB. On 05/13/10, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictated, "She did about eight weeks of physical therapy and is no better. Her pain is in the lower back, radiates to her lower leg. My recommendation at this point, having failed conservative treatment, she needs to get an L-Spine MRI."
- CC. Of note, Dr. Durrani stated that Ms. Koch completed eight weeks of physical therapy between the day he prescribed therapy on 04/18/10 and 05/13/10. Dr. Durrani's deeming physical therapy ineffective is misleading and inaccurate, as right weeks of physical therapy could not have been completed in less than a month's time.
- DD. On 05/21/10, Ms. Koch completed an L-Spine MRI, ordered by Dr. Durrani. The MRI revealed status post left laminectomy L4-5 without recurrent disc herniation. Shallow concentric disc displacement with left paracentral annular rent and mild facet arthropathy results in mild inferior foraminal narrowing without nerve root compression. L3-4 shallow broad-based disc displacement with mild facet arthropathy mildly narrows the inferior neural foramina without nerve root compression.
- EE. Of note, the MRI is showing a left L4-5 laminectomy postoperatively. Dr. Durrani dictated in his Operating Room notes, and the Koch's signed an informed consent, for a microdiscectomy on 12/07/10.
- FF. On 05/27/10, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictated, "We got an MRI which shows that foramina at the L4-5 on the left side in zone 2, and zone 3 is pretty tight, and she has recurrent stenosis from primarily the facet

hypertrophy at that level. My recommendation at this point for her, having failed conservative treatment, is to do a lumbar hemilaminectomy and discectomy on the left side at L4-5."

GG. On 09/20/10 at UC West Chester Hospital, Ms. Koch had surgery completed by Dr. Durrani. No signed hospital surgical consent produced by UC West Chester Hospital. "Dr. Durrani lists procedures performed as "Lumbar laminectomy L4-5, lumbar discectomy L4-5, left sided".

HH. Ms. Koch states, "When I went in for surgery, my legs were almost completely numb, and I was in a lot of pain. About three days after surgery, when I started walking more, my legs started giving out more and more. It was to the point to where I would fall because they would give out, not mentioning the pain that I was in."

II. On 10/04/10, Ms. Koch attended her two week post-operative visit with Dr. Durrani. Dr. Durrani dictates, "Prior to surgery, she only had left leg pain. She was doing phenomenal in the hospital. She comes in today stating that now she is doing much worse. She now has pain radiating down both legs. She has been lifting her baby girl, who weighs approximately 35 pounds. She has been chasing after her. Now she is having an exacerbation of her symptoms now in both legs. She is rating her pain a 7/10 in legs, and a 5/10 in the back. Wound looks great at this point. Amanda does have extreme pain with flexion. Back brace to be worn, start Neurontin and another Medrol Dosepak. I told Amanda to try and take it easy in the next few weeks. She is going to call me if this leg pain persists, and at that point we will get a lumbar MRI, if pain persists and is unrelenting. If pain subsides, we will see her back in three months".

JJ. Of note, Dr. Durrani references Ms. Koch lifting and caring for her toddler daughter immediately after surgery. Dr. Durrani failed to properly educate Ms. Koch and her family (since Ms. Koch was still a minor) pre and postoperatively about the lifting restrictions after surgery.

KK. On 11/05/10, Ms. Koch completed an L-Spine MRI, ordered by Dr. Durrani. The MRI revealed "L4-5 left laminectomy. Shallow protruding disc more prominent leftward with punctuate-sized left paracentral annular rent. Facet arthropathy with mild narrowing of the inferior portion of the foramina bilaterally without nerve root compression. The protruding disc abuts the descending left L5 nerve root. Interval change with the presence of fluid at the laminectomy site. This most likely represents a sterile seroma; however, contrast-enhanced imaging is recommended to exclude an abscess.

LL. On 11/16/10, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictates, "She is complaining of completely different pain now which starts from the midthoracic at the level of her bra strap level, radiates down, and then both her legs go numb. This is a new pain she did not have before. She points toward the midthoracic area as the site of pain, with pain radiating down both legs. The previous site of L4-5 laminectomy is absolutely fine. The L-Spine MRI is within normal range. This is completely different pain than what she had before surgery. My feeling is that she has some thoracic disk herniation, which is causing spinal cord compression. T-Spine MRI urgently ordered."

MM. Of note, the T-Spine MRI has not been disclosed.

NN. On 11/23/10, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani states, "T-Spine MRI was essentially within normal range. As I stated before, her L-Spine MRI was completely normal last time other than the previous laminectomy she had done. My recommendation at this point for her is to start her in physical therapy, and we will re-evaluate her in about three months".

OO. On 10/25/11, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani states, "She is almost about one year now status post left sided L4-5 microdiscectomy. Unfortunately, five weeks after surgery, she got pregnant and was not able to involve in any rehab activities whatsoever. Today she is still complaining of a lot of back pain. The leg pain seems to have significantly improved. On exam today, she is very tender in the back. All motion of the back is painful and restricted. X-rays of the L-spine show evidence of previous hemilaminectomy on the left side at the L4-5 level. There is no evidence of instability. My recommendation at this point for her is to start on physical therapy. I also asked her to see our pain physician and get enrolled with our pain service."

PP. Ms. Koch states, "I went to see Dr. Durrani again because the pain was unbearable. He and Dr. Tayeb started the injections, which I had no relief from. I had kept telling them that and they still wanted me to continue getting them."

QQ. On 01/12/12, Ms. Koch completed a right L5-S1 epidural steroid injection, given by Dr. Tayeb. Ms. Koch reports not much relief.

RR. On 02/06/12, Ms. Koch completed a right L5-S1 transforaminal epidural steroid injection, given by Dr. Tayeb. Ms. Koch reports 50% relief of pain.

SS. On 03/01/12, Ms. Koch completed a right L5 epidural steroid injection, given by Dr. Tayeb. Ms. Koch reports not much relief.

TT. On 03/26/12, Ms. Koch completed a left sacroiliac joint injection, given by Dr. Tayeb. Ms. Koch reports 75% relief of pain.

UU. On 04/13/12, Ms. Koch completed a right sacroiliac joint injection, given by Dr. Tayeb. Ms. Koch reports 75% relief of pain.

VV. On 05/25/12, Ms. Koch completed an L-Spine MRI, ordered by Dr. Tayeb. The MRI revealed L4-5 left hemilaminectomy, shallow disc bulge with curettage site or annular rent abutting dural sac and left S1 nerve root. Negative for dominant or neutrally compressive disc herniation throughout lumbar spine. Appearance of discs is unchanged from November 2010 MRI. Previously depicted fluid collection at L4-5 left laminectomy site has resorbed in the imaging interval; is not currently present.

WW. On 05/29/12, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictates, "Amanda is here for repeat evaluation. She had the left sided hemilaminectomy done about two years ago. She was doing well, and prior to that she had another laminectomy done in 2007 as well. She is now having pain in the right side in the right lower extremity, which is different than what she was having preoperatively on the left side. She has been seen by our pain physician, has gotten multiple, multiple injections. Does not seem to be getting much better. The L-Spine MRI was reviewed today, which shows a prior hemilaminectomy on the left side. There is definitely bilateral foraminal

stenosis at the L4-5, both on the right and left, but clearly the right one seems to be more symptomatic at this point. I am going to get a foraminal injection at the L4-5 on the right side, and I told her to keep a diary of pain, to see how much the pain goes away. If the pain does go away, which she has already tried multiple epidurals in the past, then I think she would be a candidate for lumbar hemilaminectomy, foraminotomy on the right side at the L4-5, if that level is proven from the injections."

XX. On 06/07/12, Ms. Koch completed a left L4-5 epidural steroid injection, given by Dr. Tayeb. Ms. Koch reports not much relief.

YY. On 06/18/12, Ms. Koch completed a trochanteric bursa injection by ultrasound guidance, given by Dr. Tayeb.

ZZ. On 06/19/12, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictates, "At this point, she got a foraminal injection and unfortunately, did not get any relief from the injection. Now she is to the point the legs are buckling under her. She still has very significant radicular pain that is going down the right lower extremity at this point. Please note, the prior pain was on the left side. The MRI shows right sided lumbar disc herniation at L4-5. At this point, my recommendation is to do a lumbar hemilaminectomy, foraminotomy, and decompression on the right side at the L4-5."

AAA. Of note, Dr. Durrani's interpretation of the L-Spine MRI is a stark contrast to the radiology read, regarding a right sided lumbar disc herniation at L4-5.

BBB. On 06/25/12, Ms. Koch completed a trochanteric bursa injection by ultrasound guidance, given by Dr. Tayeb.

CCC. On 08/14/12, Ms. Koch attended a follow up visit with Dr. Durrani. Dr. Durrani dictates, "She is having significant left sided radicular pain again. It alternates between her left and right; today it was the left that was by far more involved. Surgery to be scheduled."

DDD. Ms. Koch states, "Then Dr. Durrani ordered another surgery, and I am in more pain now than I have ever been in my life."

EEE. Of note, a generic CAST generated informed surgical procedure consent form signed by Ms. Koch's stepfather with no date or surgical procedure filled in was found in Ms. Koch's medical paperwork. This illegal procedure has been found in several other patients we are representing.

FFF. On 08/17/12 at UC West Chester Hospital, Ms. Koch had surgery completed by Dr. Durrani. No signed hospital surgical consent produced by UC West Chester Hospital. "Dr. Durrani lists procedures performed as "Lumbar hemilaminectomy L4-5, bilateral, lumbar foraminotomy L4-5, bilateral, lumbar lateral recess decompression L4-5, bilateral, lumbar lateral recess decompression, right side using Baxano".

GGG. Of note, Dr. Durrani's 08/17/12 OR dictation is another example of the copy and paste laminectomy reports found in similar cases, such as James Brown

Jr, Lisa Compo, Jessica Hastings, Dorothy Rose, and David Smith. Exact same sequence of sentences, wordage, and adjectives.

HHH. Additionally, Dr. Durrani also did not inform Ms. Koch that he was a novice at the Baxano procedure, that Dr. Durrani had only recently been trained on the procedure, and that he had not performed very many of the procedures with Io-Flex. Dr. Durrani also did not inform Ms. Koch that Baxano representatives would be present during the surgery to observe the surgery.

III. On 08/28/12, Ms. Koch attended her initial post op visit with Dr. Durrani. Dr. Durrani states, "She is now two weeks status post an L4-5 lumbar foraminotomy and decompression. She is doing very well. The left leg is completely recovered; the right leg is showing a little bit of paraesthesias still, but is definitely better than preop. Begin physical therapy."

JJJ. On 10/18/12, Ms. Koch attended a pain management appointment with Dr. Tayeb. Dr. Tayeb dictates, "She did have surgery with Dr. Durrani on 08/17/12, which resulted on her left leg feeling slightly better, but her right leg feeling much, much worse than what it previously had been. She describes her overall pain at this point as a sharp, shooting, tingling, and throbbing pain that she rates at a 9/10."

KKK. Of note, Ms. Koch's post-operative symptoms are similar to another patient of Dr. Durrani's that Baxano was used on, named Jason Romer. During a Dec. 23, 2011 surgery, Dr. Durrani improperly and negligently sheared off too much of Jason Romer's vertebrae using the new Baxano Io-Flex system, forever compromising the structural integrity of Jason's lumbar spine.

LLL. On Jan. 3, 2011 Jason reported for his first post-operative office visit with Dr. Durrani at CAST. Jason could barely walk or stand. Jason had new, different pain and had new symptomology and now had radiating pain into his left leg, which he had never had before Dr. Durrani's surgery. Despite this, Durrani documented that Jason was progressing and was "doing well at this point."

MMM. The initial MRIs ordered by Dr. Durrani at Ms. Koch's initial consultation show a normal thoracic and lumbar spine. The first abnormal radiology is an L-Spine MRI on 07/01/09, AFTER Dr. Durrani operated on her. The lack of radiology results and minimal conservative treatment deem all three surgeries medically unnecessary.

NNN. Dr. Durrani discussed the possibility of needing surgery at the second office visit on 11/15/07.

OOO. No hardware implanted in any of the three surgeries, according to implant logs.

PPP. No rhBMP-2 or Puregen usage in any of the three surgeries, according to implant logs.

QQQ. Initial surgery completed on 12/10/07, and the OR report was dictated on 12/22/07. Second surgery completed on 09/20/10, and the OR report was dictated on

11/03/10. Third surgery completed on 08/17/12, and the OR report was dictated on 08/20/12.

RRR. Ms. Koch is in the process of looking for another doctor.

SSS. Ms. Koch states, "I don't hardly sleep. I'm lucky if I get two hours of peaceful sleep without my legs throbbing and going numb, not including the pain that I am in. I went to college for phlebotomy, and couldn't finish because I was drawing blood on someone, then went to turn to put the needle in the tube, and then my legs went numb, and made me drop to the floor. So my instructor advised me to go home and come back when it was fixed, which it hasn't been. I am a mother of two, and can't perform basic things with my kids because of the pain in my back and legs. I wish I wouldn't have had any of those surgeries, or injections. I feel like it has ruined my life. I can't do the things other people my age can do, and it is not fair because he was supposed to fix it, and now it's worse than ever."

12. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani and Cincinnati Children's Hospital which proximately caused harm to Plaintiff:

- A. Unnecessary surgery(s). Number of surgeries- Three, Number unnecessary_____
- B. Need to have additional surgery to repair problems created by Dr. Durrani
- C. Implantation of BMP-2 without informed consent
- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care
- I. Negligent surgical techniques
- J. Failure to maintain accurate and complete surgical records and surgical consent forms
- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary

- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- FF. Failure by Dr. Durrani at CCH to perform accurate and complete preoperative teaching

- GG. Failure by Dr. Durrani at CCH to properly educate patient regarding diagnoses
 - HH. Failure by Dr. Durrani at CCH to maintain accurate and/or complete medical records
 - II. Failure of informed consent by Dr. Durrani at CCH
 - JJ. Failure of CCH to insure Dr. Durrani and CAST had obtained proper informed consent
 - KK. Failure of CCH to obtain proper acknowledgement of consent
 - LL. Failure by Dr. Durrani at CCH to disclose pertinent health information
 - MM. Failure by CCH to disclose additional/changed procedure and reason to patient
 - NN. Failure by CCH to supervise staff
 - OO. Failure by CCH staff to properly document abnormalities and follow up care
 - PP. Non-approved hardware combinations
 - QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Amanda Koch and concealed material facts he had a duty to disclose. CCH and CAST concealed material facts they had a duty to disclose. Amanda Koch was justified in relying on the misrepresentation and did rely proximately causing harm to Amanda Koch. Dr. Durrani and CCH intentionally misled Amanda Koch. Amanda Koch had the right to correct information.
13. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to CCH pertaining to the claims against them. CCH's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. CCH are both being referenced when only CCH is named. I hold the following opinions relative to CCH pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani joined Children's Hospital until he left by January 1, 2009. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

1. CCH's motive for their actions and inactions towards Dr. Durrani was financial gain.
2. The MEC, administration and Boards of CCH failed to "govern the affairs of the Medical Staff."
3. The MEC, administration and Boards of CCH failed to enforce their rules upon Dr. Durrani as they were required to do.
4. The MEC, administration and Boards of CCH failed to provide oversight of Dr. Durrani as they were required to do.
5. The MEC, administration and Boards of CCH failed to properly evaluate Dr. Durrani.
6. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
7. The MEC, administration and Boards of CCH failed to properly discipline Dr. Durrani including summary suspensions and revocation.
8. The MEC, administration and Boards of CCH failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
9. The MEC, administration and Boards of CCH ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
10. The MEC, administration and Boards of CCH failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
11. The MEC, administration and Boards of CCH certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
12. The MEC, administration and Boards of CCH failed to act on Dr. Durrani's failure in medical record documentation.
13. The MEC, administration and Boards of CCH failed to require Dr. Durrani to follow the rules for off label experimental procedures.
14. The MEC, administration and Boards of CCH allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including fellows and interns.

15. The MEC, administration and Boards of CCH allowed Dr. Durrani to do multiple surgeries at once.
16. CCH have refused to provide as privileged the peer review information from CCH for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
17. Based upon all of the above, it's my opinion that CCH were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at CCH under the standards of Ohio and this proximately caused harm to Plaintiff.
18. The facts support Amanda Koch's claim for negligence, battery, lack of consent and fraud.
19. As a result of the negligence and conduct of Dr. Durrani and CCH Amanda Koch suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT



KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 12 day of ~~June~~^{August}, 2014.

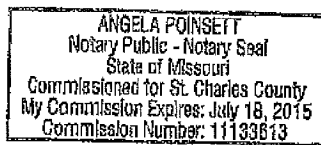
Angela Kay Poinsett

NOTARY PUBLIC

My Commission Exp. 07/18/2015

St. Charles County

State of Missouri



Oct 24 2013 2:35PM HP LASERJET FAX

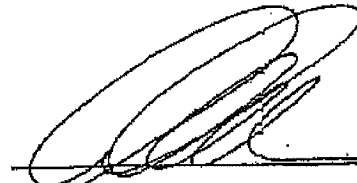
p. 2

Affidavit of Merit

I, Andrew Collier, M.D., after being duly sworn and cautioned state as follows:

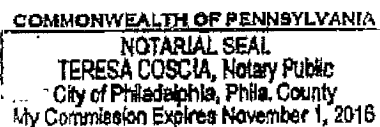
1. I have reviewed all relevant medical records reasonably available about Amanda Koch concerning the allegations of medical negligence.
2. I am familiar with the applicable standard of care.
3. Based upon my review of this record, my education, my training, and experience, it is my belief, to a reasonable degree of medical probability that the care provided by the Defendants Dr. Durrani, CAST, Cincinnati Children's Hospital, Chester Hospital and UC Health was negligent and this negligence caused injury to Amanda Koch, *inter alia*, negligent surgery; medically unnecessary surgery; negligent surgical techniques; failure to maintain accurate and complete surgical records; negligent selection and implantation of hardware; failure to obtain proper informed consent to use, and the use of unapproved allograft/hardware combination; failure to obtain proper informed consent to use, and the use of BMP-2 in a child; failure to obtain proper informed consent to use, and the use of BMP-2 on multiple levels during the same surgery; failure to obtain proper informed consent to use, and the use of BMP-2 multiple times on the same patient; failure to provide adequate/complete pre and post operative medication education and monitoring; failure to obtain proper informed consent to use, and the use of BMP-2 in the cervical spine; negligent use of "cut and paste" operative reports; medical record fraud; improper use of the Baxano decompression system; lax and substandard recordkeeping; failure to supervise Dr. Durrani; negligent pre and post surgical diagnosis; improper documentation; health care fraud; battery; negligent treatment; negligent surgery; and medical negligence.
4. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or to its instruction in an accredited school.
5. My curriculum vitae is attached.

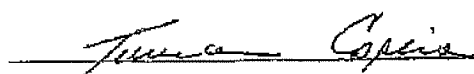
FURTHER AFFIANT SAYETH NAUGHT.


Andrew Collier, M.D.

STATE OF PENNSYLVANIA)
COUNTY OF PHILADELPHIA)

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED, before me, a Notary Public, by Andrew Collier, M.D. on the 24 day of OCTOBER, 2013.




Notary Public
My Comm. Exp. NOVEMBER 1, 2016

**RUVIMBO NYEMBA
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 200 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges. I have also reviewed binders provided by the Deters Law Firm which they provided to defense counsel.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Ruvimbo Nyemba and the medical treatment of Ruvimbo Nyemba at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.

11. I have also reviewed the nursing summary prepared by legal counsel's office for Ruvimbo Nyemba. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.
12. Based upon my review, the following are the facts I rely upon:
 - A. Ruvimbo M. Nyemba was almost 14 year old, female, single on the day of the Dr. Durrani Surgery on 9/15/10. Ruvimbo had been recommended to see Dr. Durrani by the elementary school nurse. Ruvimbo was not having any pain issues at this time.
 - B. PMH: Other than the scoliosis, Ruvimbo was relatively healthy.
SURG HX: Right Breast reconstruction and Left breast reduction.
 - C. Ruvimbo says at first Dr. Durrani wanted to watch her growth and the curvature but then as soon as she turned sixteen then it was as if were urgent. Ruvimbo says her back pain continued with some days worse than others especially with rainy or very cold weather. Pain score 3-4/10.
 - D. Ruvimbo states Dr. Durrani did not educate her or her mother regarding the use INFUSE in patients under 21 years of age or that it should not be used in the thoracic area as well. Dr. Durrani assured them Ruvimbo would return to her usual activities within 3 weeks. When Ruvimbo returned to the office after three months and still in pain, the office staff informed her she would always be in pain after a back surgery. Ruvimbo states no one told her that pre-operatively.
 - E. Ruvimbo says that she had started to dance a little after the surgery and Dr. Durrani had requested that she participate in a CAST Commercial demonstrating how well she has done and in return they would give her a scholarship for college. Dr. Durrani assured Ruvimbo and her mother that his financial manager would draw up the paperwork. Ruvimbo states the paperwork never arrived and neither did the scholarship despite all the letters and contact her mother tried.
 - F. Ruvimbo continued her schooling and she is now a junior studying Fashion Design at Kent State University and working part-time at an Outlet Store.
 - G. 3/11/08 – Scolio Limited 1-2 V @ Cincinnati Children's Hospital
Finding/Impression: there is dextroscoliosis of the thoracic spine. When measured from T4 to T12, the angle measures 22 degrees. There is a levoscoliosis of the

thoracolumbar spine. When measured from T11 -L4 angle measures 27 degrees. There is a pelvic tilt with the right iliac wing 8mm higher than the left. The lungs are clear and there is a nonobstructed bowel gas pattern. On the lateral image there is straightening of the thoracic kyphosis and lumbar lordosis. (Included)

- H. 3/11/08 – In a Cincinnati Children's Hospital Clinic note dictated by Dr. Albert Chavanne, Ruvimbo was a 13 year 5 month old healthy female. He notes that brace treatment at this time was no longer an option even though she is still a Risser grade 1. Dr. Chavanne states Ruvimbo was approaching the surgical indication cut-off and he wanted to observe her closely for the progression of her scoliosis for another six months. If there should be progression he would recommend surgery. Ruvimbo had no restrictions. This note was signed by Dr. Durrani.
- I. 7/4/08 – In a Cincinnati Children's Hospital Clinic note dictated by Dr. Durrani who documented Ruvimbo thoracic curve was about 35 degree and a 30 degree lumbar curve with no complaints of pain. She is to return in six months.
- J. 9/23/08 – Scolio Limited 1-2 V @ Cincinnati Children's Hospital
Findings/Impression: There is a 29 degrees dextro curvature of the spine from superior endplate of T4 to the superior endplate of T12. There is a 33 degrees curvature of the spine from the inferior endplate of T11 through the superior endplate of L4. (Included)
- K. 11/24/09 – Diagnostic Scoliosis Survey @ West Chester Medical Center
Findings/Impression: AP and Lateral views of the thoracolumbar spine demonstrate a dextroscoliosis of the thoracic spine of approximately 32 degree measured from the superior endplate of T5 through the superior endplate of T12. Associated compensatory levoscoliosis of the lumbar spine of approximately 33 degree measured from the superior endplate of T12 through the superior endplate of L4. Vertebral bodies are normal in appearance. (Included)
- L. 11/24/09 – In a Cincinnati Children's Hospital Clinic note dictated by Dr. Durrani that Ruvimbo had returned asymptomatic and his recommendation was for her to continue following up and return in six months. Dr. Durrani states the x-rays taken that day showed a 30 degree thoracic curve and a 37 degree thoracolumbar curve with a Risser grade 4 at this time.
- M. 5/25/10 – Scoliosis Survey Six Views @ West Chester Medical Center
Impression: Moderate thoracolumbar scoliosis present. Thoracic scoliosis is present, concave towards the left. Measuring from the superior endplate of T5 to the superior endplate of T2 has done previously, this gives angle of 32 degree similar to previous study.

- N. Scoliosis of the lumbar spine measured from the superior end plate of T12 to the superior end plate of L4 as done previously gives an angle of approximately 31 degree unchanged. Moderate thoracolumbar scoliosis is similar to prior study of November 2009. (Included)
- O. 5/25/10 -- In a Cincinnati Children's Hospital Clinic note dictated by Dr. Durrani states Ruvimbo's scoliosis had gotten worse and her curvatures had increased to 40 degrees thoracic and lumbar with a Risser grade 3. It was during this visit that Dr. Durrani had recommended doing a posterior spinal instrumentation and stabilization of the scoliosis deformity.
- P. 9/2/10 -- In a Cincinnati Children's Hospital Clinic note dictated by Dr. Durrani stated Ruvimbo was there for a pre-op discussion of her upcoming posterior spinal instrumentation and fusion. She was to be scheduled.
- Q. 11/20/10 -- Physical Therapy Discharge Summary was dictated by Paul Boys, PT,MHS who stated this was Ruvimbo's last PT visit. Paul states Ruvimbo had absolutely no lower extremity symptoms or thoracic pain. Ruvimbo had been reporting periodic spasms in her left scapular area and upon exam she had exaggerated left scapular protraction compared to the right. Paul had shown Ruvimbo the prone Blackburn exercises performed on a weight bench. She was able to do ten repetitions along with the stabilization exercise with the marching. She was discharged with a home exercise program focusing on continuing to increase her hip strength and her scapular tone.
- R. 12/16/10 -- Diagnostic Scoliosis Survey @ West Chester Medical Center
Impression: * Status post posterior thoracolumbar fusion from T4 through L1 without evidence of hardware complication.
- Unchanged mild dextroscoliosis of the thoracic spine with mild levoscoliosis of the upper lumbar spine.
 - Pectus excavatum. (Included)
- S. 12/16/10 -- Dr. Durrani dictates Ruvimbo was s/p a MIS posterior instrumentation spinal fusion and that she was doing very well and hardly taking any pain medication. Dr. Durrani states the x-rays taken showed excellent correction of the deformity and the lumbar curve itself was almost pretty straight. This was the last Durrani note in the file.
- T. 8/29/11 -- CT Lumbar Spine, CT Thoracic Spine w/o Contrast and CT-3D Rendering on Modality @ West Chester Medical Center
Thoracic CT Impression: * Status post posterior fusion from T4 to L1 levels. Mild dextroscoliosis of the thoracic spine.

- The T4 screws course medial to the T4 pedicles and moderately encroach on the right and left lateral aspects of the spinal canal. The left T5 pedicle screw courses along the inferior aspect of the left T5 pedicle and mildly encroaches on the superior aspect of Left T5 foramen.
(Included)

U. Lumbar Spine CT – Patient is s/p thoracolumbar fusion. There is mild levoscoliosis of the lumbar spine. Fusion extends inferiorly to the L1 Level. Hardware at the T12-L1 level appears intact and does not appear to encroach on the central canal or neural foramen.
Impression: Mild levoscoliosis of lumbar spine.
(Included)

V. CT-3D Rendering on Modality –

Findings/Impression: * Axial CT was performed through the thoracic and lumbar spine. Sagittal and coronal reconstructions were obtained. 3D reconstructions were also obtained. There is mild dextroscoliosis of the thoracic spine and mild levoscoliosis of the lumbar spine.

- The patient is s/p fusion from the T4-L1 levels. Posterior rods are transfixed by transpedicular screws at the T4, T5, T8, T9, T10, T12 and L1 levels. The hardware appears intact. There is no evidence of loosening.
- The T4 screws course medial to the T4 pedicles and moderately encroach on the right and left lateral aspects of the spinal canal. The left T5 pedicle screw mildly encroaches on the superior aspect of the left T5 foramen.

(Included)

W. It is apparent that this surgery was medically necessary but not for Dr. Durrani to use BMP2/INFUSE on this patient who was under age for this INFUSE usage and utilizing it in an area where it had not been FDA approved was wrong.

X. Dr. Durrani's misinterpretation of the pre-operative diagnostic:
11/24/09 Dr. Durrani misquotes the results of the x-rays taken that day, x-rays stating the curvature was then 32 and 33 degrees and Dr. Durrani stated the curvatures were 30 and 37 degree and she was a Risser grade 4. This Risser grade decrease in the following months per Dr. Durrani.

Ruvimbo had been a patient of Dr. Durrani's at Cincinnati children's hospital and had been followed for several years prior to the initial surgery.

Y. Dr. Durrani performed one surgery on this client:

9/15/10 – Surgery @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES:

- Adolescent Idiopathic Scoliosis

PROCEDURES:

- Posterior Spinal Instrumentation using pedicle screws from T4-L1
- Posterior Spinal fusion using auto & allograft T4-L1

There is no West Chester Medical Center's Informed Consent available in this file and no Radiologist available during the surgery.

Z. BMP-2 was used during surgery.

AA. The following hardware was implanted:

- 1 – INFUSE Set Bone Graft LG – Medtronic
- 1 – bone Graft Sub Vitoss 25 x 240 x 4 – Orthofix
- 10 – 6.0 x 40 Viper Screws – Depuy Spine
- 4 – 6.0 x 35 Viper Screw – Depuy Spine
- 3 – Titanium Rod 5.5 Diameter – Depuy Spine
- 14 – Viper Set Screws – Depuy Spine

BB. It was “off-label” and prone position.

CC. The Operative Report was dictated by Dr. Durrani on 11/3/10 (47 days later) and it was verified on 11/12/10 (58 days later).

DD. Ruvimbo did have a right breast reconstruction for a developmental deformity with liposuction fat injections. Later on she had a reduction in the left breast to equalize her breasts. Both procedures were done by Dr. Ann Schwentker, Plastic Surgeon in 2013 at Cincinnati Children's Hospital.

EE. Ruvimbo states she is having more pain than before surgery in fact she was not having any pain at all before the surgery.

FF. Ruvimbo states she use to ride a bike and running which is difficult because her duration has decreased. Ruvimbo says her low back pain continues until today and some days are worse than others especially the sharp pain in the right upper back and her lower back aches all the time. She rates her pain 4/10 all the time. She has other limitations as a result of the surgery:
Walking – was easier before the surgery and now after about 1 hour she begins to feel discomfort.
Sitting – was not a problem in school until after the Durrani surgery and now she can only about an hour or two and then her back pain increases.
Standing – for about 1-2 hours, like in the shopping mall, then her back increases.

Laying down and sleeping on her stomach without a pillow under her head is the only comfortable position that allows her to fall asleep without any kind of medication.

Sleeping- was interrupted at least 1-2 times a night and her sleep was quite restless most nights.

Lifting limit – is done cautiously especially with heavier items like a heavy laundry basket.

Household chores – she is able to do most of them but after awhile she will rest periodically.

Able to drive – she is able to drive but not on long car rides of which she has to get out and stretch at least every 2 hours.

Flexion – she finds looking down and just leaning forward seem to trigger right sided pain in her back. She is able to sit down and tie her shoes and able to bend over and pickup something off the floor but not anything heavy.

GG. Ruvimbo finds that sitting on a softer type of chair or couch is more comfortable for her than a harder surface one.

HH. Ruvimbo seems to be a positive person and does not quite understand why Dr. Durrani did what he did knowing she would always be somewhat in pain apparently for the rest of her life.

13. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff.

- A. Need to have additional surgery to repair problems created by Dr. Durrani
- B. Implantation of Puregen without informed consent
- C. Implantation of BMP-2 without informed consent
- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care
- I. Negligent surgical techniques

- J. Failure to maintain accurate and complete surgical records and surgical consent forms
- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary
- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses

- DD. Failure to attempt non-surgical conservative treatment
 - EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
 - FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
 - GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
 - HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
 - II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
 - JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
 - KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
 - LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
 - MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
 - NN. Failure by UC/West Chester Health to supervise staff
 - OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care
 - PP. Non-approved hardware combinations
 - QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Ruvimbo Nyemba and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Ruvimbo Nyemba was justified in relying on the misrepresentation and did rely proximately causing harm to Ruvimbo Nyemba. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Ruvimbo Nyemba. Ruvimbo Nyemba had the right to correct information.
14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against

West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.

15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.
5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.
7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr. Durrani. This infers a poor environment of honesty and disclosure before this policy.
9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.

10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.
11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.

26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.
27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.

41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.

57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

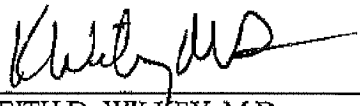
ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.
66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."

68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to provide oversight of Dr. Durrani as they were required to do.
70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.
78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including Dr. Shanti.
80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.

81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Ruvimbo Nyemba's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Ruvimbo Nyemba suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT

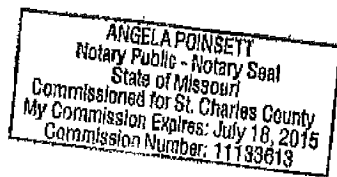


KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 4 day of ^{May}~~April~~, 2015.



Angela Poinsett
NOTARY PUBLIC
My Commission Exp.: 07/18/2015

St. Charles County

State of Missouri

**RONALD ROWLEY
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Ronald Rowley and the medical treatment of Ronald Rowley at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.
11. I have also reviewed the nursing summary prepared by legal counsel's office for Ronald Rowley. Based upon the number of cases I've reviewed pertaining to Dr.

Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

12. Based upon my review, the following are the facts I rely upon:

- A. Ronald Rowley is now a 48 year old male, divorced and has custody of his 14 yr old daughter. Ronald's work career centered around factory work and being a cook which required him to stand on his feet all day long. He is a recovering alcoholic and was pursuing an Associate's Degree in Chemical Dependency at Southern State College prior to surgery. He was suffering from lower back pain shooting down his legs (right Sciatic more so) with numbness, tingling, left knee pain and increased urinary frequency. Over the years to deal with the pain Ron misused drugs and has been involved with CAST's Pain Management group (Dr. Tayeb).
- B. Upon referral from his PCP, Dr. John Merling, he sought Dr. Durrani's opinion. Ronald states "Dr. Durrani assured him he could fix him and he would have no more pain." In a note to Dr. Merling (3/25/10) Dr. Durrani states Ron was also having trouble with uncontrolled loss of stool, dropping things and had been through unsuccessful conservative treatments for many months. Ron says this is not true regarding the stool, dropping things and conservative treatment. His pain score pre-op was 8/10.
- C. Ron says Dr. Durrani was highly recommended and he believed what Dr. Durrani conveyed to him regarding the surgery. Ronald also states that Dr. Durrani never told him anything about using any type of cement (auto/allograft) or actually taking the disc out. Ron has since discovered that the side effects of INFUS/BMP can cause cancer later on in life and now he is very anxious and worried this may potentiate his chances of happening, since cancer runs in his family.
- D. In a 3-month (1-13/11) post-op note to Dr. Merling, Dr. Durrani states Ronald is doing very well with negligible pain. Ron stated this is not true at all, that he actually developed anxiety and depression over the months following surgery due to the unrelenting pain he endured. He has even experienced panic attacks and has frequent the ERs for both pain and mental health issues, of which he continues to be treated.

- E. Since his inability to do this type of work with the increased pain he has in his legs along with anxiety and panic attacks he now experiences, he has finally been given Social Security Disability as of early 2013.
- F. According to the Radiology readings it does not appear to have been necessary at the time.
- G. Dr. Durrani misinterpreted the pre-operative diagnostic. On 2/16/10 MRI Lumbar Spine from the Clinton Memorial Hospital: Impression: L4-L5 level, there is a right paracentral/right subarticular/right foraminal disc protrusion causing mild to moderate right foraminal narrowing and causing mild posterior displacement of the descending right L5 nerve root in the right lateral recess. (included)
- H. According to Dr. Durrani's note (3/25/10) to Dr. Merling, he states "the x-rays reviewed that day show Ronald has L4-L5 degenerative listhesis. That the MRI showed a very large disk herniation at L4-L5 which completely obliterating the right foramina at that level. He has a very significant central foraminal stenosis at that level. The MRI also shows a massive arthropathy at the L4-L5 level. Mild degenerative changes at L3-L4 as well.
- I. In the same note, Dr. Durrani's clinical opinion was lumbar spinal stenosis and spondylolisthesis @ L5-S1, progressive severe central neurogenic claudication, back pain, radicular pain in the L4=L5 distribution, very significant function impairment, anterolisthesis of L4-L5, central and lateral recessed stenosis L4-L5 more predominant on the right side.
- J. Dr. Durrani recommended surgery on the first office visit. Ronald states he did not offer any kind of injections/blocks or anything else at that time, just surgery.
- K. Dr. Durrani performed one surgery on the client:
On 8/25/10 SURGERY @ West Chester Medical Center
PROCEDURES: 1) Lateral Lumbar Interbody fusion L4-L5 using Auto/allograft
2) Placement Lateral Interbody Cage L4-L5
3) Posterior Spinal Instrumentation, L4-L5
4) Posterior Spinal Fusion using Auto/allograft
- L. The Informed Consent in the Medical Records is Blank as far as the type of procedure/surgery but it was signed by Ronald Rowley and Dr. Durrani on 8/12/10. Although in Dr. Husted OR dictation he notes after obtaining informed consent, the patient was taken to the operating room etc.. In the Intra-op Report it

is recorded during the time-out period the staff compares the upcoming procedure with the Informed Consent. (page 361)

- M. The Informed Consent (page 361, the only consent in this medical record) details all the risks, consequences, complications and alternatives of the operative procedure but does not identify what procedure/procedures the patient has consented to be performed and it is witnessed by apparently Dr. Durrani's signature dated 8/12/10.

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME
Lumbar 4- lumbar 5 Degenerative disk disease, Degenerative Spinal stenosis.

- N. INFUSE/BMP2 was used.

- O. The following hardware was implanted:

5cc – foam Bioact Vitoss
1 – Clydesdal 12X50mm Medtronic
4 – Set Screw F/G4 INT HEX Medtronic
2 – Rod Pre Bent M* 5.5X40mm TI Medtronic
1 – INFUS Set Bone Graft Sm Medtronic

- P. Off label use: It was an anterior exposure with a DLIF approach with cage.

- Q. Surgery was on 8/25/10 and the Op Report was dictated by Dr. A. Durrani on 11/1/10 (68 days later) and verified by Dr. Durrani on 11/12/10 (79 days later).

- R. There was no failed hardware. If the client continues to be in more pain than before the surgery perhaps that constitutes a failure.

- S. The client states he has no insurance yet and cannot afford financially to seek another opinion at this time. At one of the ER visits he was told that it wasn't understood why the surgery was done in the first place because it really was not necessary at the time according to the MRI of 2/16/10.

- T. Ronald states he is having more pain now than prior to the surgery. He rates his pain score as 7-9/10 on a daily basis. On some days his pain level is up to 10/10 for whatever the reason.

- U. Ronald feels as though Dr. Durrani has impacted his life greatly not only with the daily pain he has to deal with but the anxiety and panic attacks that continue to occur. He is no longer able to stand to perform the jobs he had been accustomed to for the first 25 years of his work-life.

- V. He wants to try to get another surgeon's opinion regarding removal of the BMP/INFUS or what else could be done if anything to alleviate the back pain and the urinary frequency. His limitations currently are:

Walking – before surgery he could walk 2-3 hours but not now he is not able to walk more than 15 minutes at a time and that's with a cane.

Sitting – he was able to sit for 2-3 hours before changing position and now its only 45-60minutes until his buttock becomes numb with a deep throbbing aching pain. He was told by an ER physician he has now severe arthritis in the Lumbar 4-5 area.

Standing – he could stand all day, 8 hours at a time at work as a cook and the factory work with no problem but now it's 5 minutes and he has to sit down.

Lying – use to be able to lay on his stomach and back but now he is limited to only his right or left sides. On his back he states like there is too much pressure.

Sleeping – he awakens every 2 hours throughout the night due to pain and needs to change positions. He has even tried his brace which doesn't seem to help with the pain either.

Lifting limit is to about 10 lbs, trying to bend forward is most difficult.

Household chores and cutting the grass responsibilities have been taken over by his significant other. He no longer drives himself due to the disability status with Social Security. He has not received Medicaid as of yet. He is limited to brief car trips and grocery shopping for the week is out of the question. He is concerned with the panic attacks that occur in relation to the severity of the pain. He has gotten very depressed over this in the last couple of years and has sought and continues with treatment. He finds himself worrying and getting anxious over the fact that the BMP could cause cancer in the future. Ron states he ends up in the ER about once a month for the pain and panic attacks. His last visit with Dr. Durrani was 1/13/11. Ron never returned for his 1 year follow-up visit.

13. Based upon my review, the following are my opinions based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:

- A. Need to have additional surgery to repair problems created by Dr. Durrani
- B. Implantation of Puregen without informed consent
- C. Implantation of BMP-2 without informed consent
- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education

- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care
- I. Negligent surgical techniques
- J. Failure to maintain accurate and complete surgical records and surgical consent forms
- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary
- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up

- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
- GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
- HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
- II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
- JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
- KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
- LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
- MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
- NN. Failure by UC/West Chester Health to supervise staff
- OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care
- PP. Non-approved hardware combinations
- QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Ronald Rowley and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Ronald Rowley was justified in relying on the misrepresentation and did rely proximately causing harm to Ronald Rowley.

Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Ronald Rowley. Ronald Rowley had the right to correct information.

14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.
15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.
5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.
7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr.

Durrani. This infers a poor environment of honesty and disclosure before this policy.

9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.
10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.
11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.
20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.

24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.
27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."
36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.

39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.
51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.

55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.

66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to provide oversight of Dr. Durrani as they were required to do.
70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.
78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries

including Dr. Shanti.

80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.
81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Ronald Rowley's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Ronald Rowley suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT

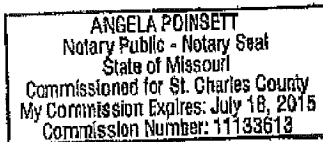


KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 13 day of October, 2014.



Angela Kay Poinsett
NOTARY PUBLIC
My Commission Exp.: 07/18/2015
St. Charles County
State of Missouri

**BILL SPIVY
AFFIDAVIT OF MERIT
WEST CHESTER**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for West Chester Hospital, LLC, also referred to as West Chester Hospital or West Chester Medical Center and UC Health.
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Bill Spivy and the medical treatment of Bill Spivy at West Chester.
9. I have reviewed the Response to Summary Judgment in the Brenda Shell case and all the exhibits attached to it.
10. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.
11. I have also reviewed the nursing summary prepared by legal counsel's office for Bill Spivy. Based upon the number of cases I've reviewed pertaining to Dr. Durrani,

legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

12. Based upon my review, the following are the facts I rely upon:

- A. Billy Spivy was a 51 year old male when Dr. Durrani did the first of three surgeries. He is now a divorced and disabled 58 year old. Billy says he was an athlete when in high school and had always kept himself in fairly good condition. He states he use to run a lot on a daily basis and would run everywhere in the town he use to live in.
- B. Billy has a medical history of Hypertension, Hyperlipidemia, Coronary Artery Disease, CHF, Gout, Hypothyroidism, Anxiety and Bipolar Disorder. Surgically he has had operations on his hands, right foot, heart and neck.
- C. Billy use to manage a restaurant with his wife for several years had to be on his feet all day long which at the time was not a problem. He fell off of a two-story roof, back in 1991 and had lumbar surgery at that time at Vanderbilt. He did fine for about 15 years then the lower back pain returned along with right leg pain and right testicle pain. That's when he saw Dr. Durrani for an opinion. Billy's pain score 8-9/10 at this time.
- D. Billy states Dr. Durrani made the decision to operate at the first office visit and before he had even gotten the first MRI. It wasn't until after the surgery when Billy saw the x-ray films that he realized what he was feeling in his back was the hardware that had been put in place. Billy adamantly states Dr. Durrani did not explain to him about any of that hardware pre-operatively. (#1 Surgery - 2/9/07)
- E. 8/16/07 in an office note, Dr. Durrani stated that Billy was pretty happy with his progress and Billy states that has never been true. Billy continued with lower back and right leg pain and with the pain medication that Dr. Durrani continued to prescribe for him for two years. When he would question Dr. Durrani regarding the constant lower back pain and now neck pain also, Dr. Durrani would tell Billy the only thing that will help is more surgery.
- F. 8/31/07 in an office note, Dr. Durrani stated Billy was complaining of significant neck pain, left arm weakness, left arm numbness and the right leg is going numb as well. Apparently there was a period of time lapse because the next office note

is 1/20/09 and again in an office note Dr. Durrani states Billy has severe cervical stenosis with intense symptoms. Dr. Durrani was so emphatic about more surgery he told Billy he would stop prescribing his pain medications unless he agreed to more surgery. So Billy agreed to the cervical surgery (#2 surgery- 3/27/09) See diagnostic films of 3/27/09 below.

- G. Dr. Durrani had told Billy it would be about a 4-5" incision in his neck and it turned out to be about 10".
- H. At the time Billy states he didn't understand how neck surgery was going to help his lower back pain and when questioning never really got an answer from Dr. Durrani or the office staff. Billy says if the office staff answered any of his questions regarding himself, the next time he visited the office that person was no longer there.
- I. Billy had to have Cardiac Clearance and the Cardiologist, Dr. Raghu would not allow for the blood thinning medication to be stopped. (Dr. Raghu had been treating Billy for his CHF and had placed cardiac stents prior to the surgery.) Dr. Durrani assured Billy by not stopping the blood thinners would be no problem. Well that wasn't true because Billy did have an episode of excessive bleeding post-operatively resulting in receiving a unit of blood and increasing the hospital stay by 5 days. Apparently one of the nurses informed Billy that he had a TIA/heart attack during both #1 and #2 surgeries that he had not been aware of. He said when he questioned personnel at Christ no one would give a straight answer.
- J. Billy's pain continued in his lower back and down his right leg so he returned to Dr. Durrani again. Billy had to go back to Dr. Durrani because once other physicians found that he had surgery previously by Durrani they refused to get involved. So Dr. Durrani had informed Billy that he was well on his way of being totally disabled if he didn't have more neck surgery which came about, (#3 surgery - 9/17/10) Another complication ensued following that surgery which was MRSA. It took 2-3 months for that infection to clear up according to Billy. See cervical diagnostic report dated 6/25/10 below.
- K. Following this #3 surgery Billy had to go to see Dr. Tayeb for 12 epidural steroid injections to try to help ease his pain. Billy stated on many occasions Dr. Tayeb wasn't even able to inject into the correct spaces due to the amount of hardware in

place. Dr. Tayeb told Billy he had the limit of injections and he would have to go his PCP, Dr. Sabir Quraishi, to get his pain medications from then on.

- L. Billy says comments made to him by personnel made him feel uncomfortable and he wondered about the competency of Dr. Durrani, i.e. Radiology staff commenting they knew who did his surgery acting like it was a funny thing; a nurse, Rosa, who had been a cardiology nurse, stated to Billy, he was just a guinea pig so-to-speak, and another nurse from Dr. Tayeb's office telling Billy all they were doing was killing him. Billy's faith and trust in Dr. Durrani began to weaken from that time.
- M. 11/16/10 in an office note, Dr. Durrani stated Billy was now having right leg pain, pain shooting down the right leg along with numbness and tingling. Billy had been complaining about this right leg pain and right testicle since the first office visit on 11/9/06. Dr. Durrani's impression of that visit was:
- Lumbar spinal Stenosis associated with lumbar spondylolisthesis L3-L4, L4-L5
 - S/P prior lumbar interbody fusion at L2-L3 and L5-S1
 - Progressive and severe symptoms of neurogenic claudication
 - Back pain with radicular pain in the L3-L4 and the L4-L5 distribution
 - Very significant functional impairment
 - Anterolisthesis of L3 on L4 and L4 on L5
 - Adjacent level degeneration L3-L4, L4-L5
 - Severe central stenosis L4-L5 and moderate central stenosis L3-L4
 - Severe foraminal stenosis bilaterally at L4-L5, moderate at L3-L4
 - Failure of conservative treatment for over many years.
- N. 2/28/11 Billy apparently had a cardiac arrest immediately following a cardiac stent placement and was resuscitated by cardiologist, Dr. Raghu.
- O. 10/2/12 In a letter to Billy's PCP, Dr. Sabir Quraishi, Dr. Durrani's stated Billy had returned with ongoing right leg pain along with it giving out on him without warning causing him to fall, 1-2X/week. Billy's forward flexion and extension both were painful. Dr. Durrani reminded Dr. Quraishi that Billy had failed cardiac clearance when he previously had Billy scheduled for lumbar surgery. His plan was to repeat a lumbar MRI and have Billy return to the office for a surgical decision. This #4 surgery was never done.

P. Billy had been complaining to his PCP that he chokes easily and has difficulty swallowing and clearing his throat. Dr. Quraishi ordered a CT of the Neck. Billy was told by a Dr. Susan that the way he holds his head and neck from the neck surgery is crunching his Thyroid. He states he is able to palpate this which then makes him nauseated.

Q. 2/12/13 CT of the Neck with IV Contrast

Impression: * Mild dorsal protrusion of the right lobe of the Thyroid, otherwise unremarkable appearance of the thyroid. * Mild enlargement of an upper jugular lymph node of each side.

- Moderate diffuse mural thickening of the upper esophagus may indicate esophagitis or severe reflux. This should be evaluated further as clinically warranted.
- Other findings including enlargement of the ascending Aorta and bony findings.

Billy's last visit to Dr. Durrani was on 3/20/13.

R. Questionable if the correct procedure was done for #1 surgery. No office note regarding Dr. Durrani's decision as to why this surgery was done at this time.

S. Dr. Durrani's misinterpretation of the pre-operative diagnostic:

#1 Surgery - 11/9/06 Scoliosis Survey done @ University Pointe

Impression: Limited examination. Very mild scoliotic curvature at the thoracolumbar junction.

Multilevel degenerative discogenic changes. Suspected transitional segment at the lumbosacral junction, considered S1 for the purpose of this examination. (included)

#1 - Surgery - 4/12/07 Lumbosacral Spine @ Adams County Hospital

Findings: it is stated there has been unilateral posterior fusion at L2-L3 with right-sided pedicle screws and a vertical bar, hardware intact. There is asymmetric loss of disc space height at L2-L3 greater on the left, resulting in degenerative scoliosis. At L5-S1 disc space has been preserved and no subluxation. (included)

#1 Surgery - 4/21/10 Lumbosacral Spine series @ The Christ Hospital

Impression: 4 lumbar type vertebral bodies, status post posterior fusion L1- L2, Prior anterior and posterior at L4-S1.

The Informed Consent does mention L1-L2 or L4.

The Informed Consent was signed for L2-L3 and L5-S1 percutaneous transforaminal lumbar interbody fusion for #1 surgery.

#2 Surgery - 8/23/07 - Cervical Spine MRI without Contrast

Impression: Post-fusion changes with diffuse posterior bulging of the fused vertebral bodies and mild narrowing of the canal at this level, other area of disc protrusion with areas of canal narrowing and mild cord volume loss. (included)

#2 Surgery – No other Radiology Reports available from 8/23/07 to the day of surgery on 3/27/09.

Page 14 is missing, but the Diag C-Spine 2-3 Views dated 3/27/09 @ Christ Hospital

Impression: Prior anterior fusion at C5-C7, Mild anterior bony spurring at C3-C4, moderate anterior bony spurring at C4-C5 and reversal of normal cervical lordosis. (included)

#2 Surgery procedure is questionable as to why it was done at that time.

#3 Surgery - 6/25/10 Cervical Spine MRI without Contrast @ Adams County Hospital

Findings: It is noted that C7-T1 is unchanged without significant canal narrowing. There is no significant foraminal narrowing. Comparison was 8/2007

#3 Informed Consent is missing. Three months later, the Op Report 9/19/10 states the procedures done were on C7-T1, anterior discectomy, fusion with Allograft and Autograft, cervical cage placement and instrumentation.

#3 Surgery procedure is questionable as to why it was done.

T. On the first office visit, Dr. Durrani recommended the first surgery.

U. Dr. Durrani performed three surgeries on this client:

#1 – Surgery – 2/6/07 @ The Christ Hospital

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Lumbar 2 – L3 Discogenic disease with stenosis
- L5 – S1 Discogenic disease with foraminal and central stenosis

PROCEDURES:

- L2-L3 Right foraminal decompression and laminectomy
- L2-L3 posterior spinal instrumentation
- L2-L3 posterior spinal fusion
- L5-S1 transforaminal lumbar interbody fusion
- L5-S1 Posterior spinal instrumentation
- L5-S1 Posterior spinal fusion

#2 – Surgery – 3/27/09 @ The Christ Hospital

PREOPERATIVE POSTOPERATIVE DIAGNOSES: SAME

Cervical Spinal Stenosis

PROCEDURES:

- C3 thru C7, Posterior Cervical Laminoplasty with Left sided opening and Right sided hinging.

#3 – 9/17/10 – Surgery - @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Cervical Degenerative Disc Disease C7-T1
- Cervical Spinal Stenosis C7-T1

PROCEDURES:

- Anterior Cervical Discectomy C7-T1
- Anterior Cervical Fusion using Autograft and Allograft C7-T1
- Anterior Cervical Placement Interbody Cage C7-T1
- Anterior Cervical Placement Instrumentation C7-T1

V. BMP-2 was used during the following surgeries:

1 Surgery – Recombinant BMP

3 Surgery – BMP, Bioact Foam, Autograft and Allograft

W. The following hardware was implanted:

#1 - Surgery - 2 – Screws 6.5x35mm - Medtronic

4 – 6.5x45 mm - Medtronic

6 – Set Screws – Medtronic

2 – Rods 45mm – Medtronic

1 – Rod 50mm – Medtronic

Master Graft Matrix

Capstone Verte-stack VBS 36x14mm

INFUSE Bone Graft Large Kit

#2 – Surgery - 3 – Plates 10mm - Medtronic

18 – Screws 7mm - Medtronic

2 – Plate 12mm – Medtronic

1 – Screw 9mm – Medtronic

#3 – Surgery – 1- Foam Bioact Vitoss Pack 5cc – Orthovita

1 – INFUSE XX Bone Graft Sm 0.7ml -0 Medtronic

1 – SPCR Vert Lord Cr 9mm Polymer – Synthes Spine

3 – Screws Cerv VA SD VECTRA 4x14 T1 – Synthes Spine

2 – Screws Cerv VA SD VECTRA 4x16 T1 – Synthes Spine

1 – Plate Cerv VECTRA 1 Lev 16mm T1 – Synthes Spine

1 – SPCR VERT Lord CR 8mm Polymer – Synthes Spine

X. Billy stated that Dr. Durrani did not explain to him that he was going to put in all that hardware, afterwards he was most upset because he had no idea until he saw his x-rays. He says the only thing he recalls was that he would have artificial

disc inserted and had no concept of what it actually involved because Dr. Durrani had not explained it to him clearly.

Y. Off-Label Use:

- #1 Surgery - was a TLIF approach
- #2 Surgery - was a posterior approach.
- #3 Surgery - was a standard right-sided Smith-Robinson approach.

Z. Operative Report Dictations:

#1 Surgery was dictated and verified by Dr. A. Durrani on 11/3/10 (47 days later).

#2 Surgery was dictated by Dr. A. Durrani on 3/30/09 (3 days later) and verified by Dr. Durrani on 6/10/09 (75 days later).

#3 Surgery was dictated and verified by Dr. A. Durrani on 11/3/10 (47 days later).

AA. The following consists of failed hardware:

#1 Surgery was going to be revised due to the continued leg pain only this time he was going to involve L4-L5, of which he skipped over on the first surgery.

BB. The client has not seen a subsequent treating physician, but Dr. Durrani had planned to do a revision of #1 Surgery – Lumbar but due to the patient's CHF he was not cleared by Cardiology for the procedure.

CC. The patient tried to see other surgeons (Mayfield Clinic) but once they found out Dr. Durrani had operated on him they refused to get involved.

DD. As Billy said it should go without saying that he has much more pain now than he ever imagined prior to Dr. Durrani's surgery. Billy states it's without a doubt that his life has been ruined by Dr. Durrani and he is not able to even do his daily living activities without help. Billy says he has now experienced what a 10 on the pain scale really is and that he has a 9-10/10 pain constantly since the first surgery. When the weather is bad his pain seems to be a 10/10 all day.

EE. Billy has had to move three times since original surgery because he then had trouble getting up and down the steps of his apartment. In the last 4 years Billy has become so debilitated from the constant pain and inability to walk. He's had to move into an assisted living nursing facility. He has an Aide that comes in every day to help him get his clothes on and get his meals for him. A nurse comes once a week for the CHF. Billy says sometimes he gets so depressed over the whole situation and having to tolerate the constant pain, he gets an occasional idea of why stick around but says he is not suicidal. His limitations are extensive these days such as:

Walking – before Durrani's surgery he use to walk everywhere for hours and now he can only manage to walk for less than 5 minutes. He walks with a cane or a walker. He states he continues to resist suggestions of utilizing a wheelchair cause he feels once he gives into it he may not be able to walk at all.

Bathing – he needs assistance with getting in and out of the shower, prone to falling of which he has frequently since his right leg continues to give out on him.

Dressing himself is a problem since he cannot raise his arms above his shoulders requiring him to have help in putting on tee shirts. When he forces himself to do this pain shoots up his neck and into his back. He suffers with headaches frequently. He is able to get his pants on but needs help in getting his shoes on.

Sitting- was not a problem before the 1st surgery but currently 15 minutes is maximum before he has to change his position.

Standing – was the usual routine since he ran a restaurant and was on his feet all day.

Laying down is limited to only his right side.

Sleeping – comes in shifts of 3 maybe 4 hours at a time then he has to get up and sit for brief period then go back to bed. At night his right leg seems to fall asleep which then awakens him.

Lifting – before all the surgeries was not a problem to lift whatever he needed to but currently is about 2-3 lbs at a time. If he attempts to pick up anything heavier he then pays for it with pain shooting up his back and neck resulting in a bad headache.

Household chores – he is not able to do on a daily basis, the Aide tends to all his needs in that aspect including mailing his bills.

Grocery shopping – the Aide does that for him also.

Flexion – of his neck is limited as well, he can turn his head a little to the right but not at all to the left. He can bend his neck forward just a little.

Shaving his neck requires assistance because he cannot bend his neck backwards.

Flexion – of his back is limited to being able to lean forward a little and is unable to bend over.

Driving – he does not do anymore because of the limited flexion of his neck, afraid he might run into another car.

FF. Billy seems to have accepted the fact he will have to live with the pain he endures every day for the rest of his life. He says at times it gets depressing. He has been told he will have to be on pain medications, muscle relaxants – Robaxin along with Neurotin and Baclofen for the rest of his life.

13. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani, CAST, West Chester and UC Health which proximately caused harm to Plaintiff:

A. Need to have additional surgery to repair problems created by Dr. Durrani

- B. Implantation of Puregen without informed consent
- C. Implantation of BMP-2 without informed consent
- D. Failed hardware
- E. Failure to obtain proper informed consent for surgery
- F. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- G. Failure to properly post-op monitor the patient
- H. Failure to properly perform follow up, post-op care
- I. Negligent surgical techniques
- J. Failure to maintain accurate and complete surgical records and surgical consent forms
- K. Failure to disclose important health information to patient
- L. Failure to maintain and complete discharge summary
- M. Failure to supervise Dr. Durrani
- N. Negligent pre-surgical diagnosis
- O. Failure to prepare a timely operative report or other medical record
- P. Billing for services not completed
- Q. Not informing the patient another surgeon will be doing all or part of the surgery
- R. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- S. Deviation in standard of care
- T. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- U. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason

- V. Failure by CAST to disclose additional/changed procedure and reason to patient
- W. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- X. Prior knowledge of possible complication and not acting properly upon same
- Y. Failure to disclose pertinent health information to another health care provider
- Z. Fraudulent, negligent and reckless pre-operative work up
- AA. Fraudulent, negligent and reckless surgery
- BB. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- CC. Failure to properly educate patient regarding diagnoses
- DD. Failure to attempt non-surgical conservative treatment
- EE. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- FF. Failure by Dr. Durrani at UC/West Chester Hospital to perform accurate and complete preoperative teaching
- GG. Failure by Dr. Durrani at UC/West Chester Hospital to properly educate patient regarding diagnoses
- HH. Failure by Dr. Durrani at UC/West Chester Hospital to maintain accurate and/or complete medical records
- II. Failure of informed consent by Dr. Durrani at UC/West Chester Hospital
- JJ. Failure of UC/West Chester Hospital to insure Dr. Durrani and CAST had obtained proper informed consent
- KK. Failure of UC/West Chester Hospital to obtain proper acknowledgement of consent
- LL. Failure by Dr. Durrani at UC/West Chester Hospital to disclose pertinent health information
- MM. Failure by UC/West Chester Health to disclose additional/changed procedure and reason to patient
- NN. Failure by UC/West Chester Health to supervise staff

OO. Failure by UC/West Chester Medical staff to properly document abnormalities and follow up care

PP. Non-approved hardware combinations

QQ. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Bill Spivy and concealed material facts he had a duty to disclose. UC/West Chester Health and CAST concealed material facts they had a duty to disclose. Bill Spivy was justified in relying on the misrepresentation and did rely proximately causing harm to Bill Spivy. Dr. Durrani, CAST, and UC/West Chester Health intentionally misled Bill Spivy. Bill Spivy had the right to correct information.

14. The testimony, facts and exhibits of Brenda Shell's Response to Motion for Summary Judgment and Exhibits to same are applicable to all the claims against West Chester Medical Center (WCMC) and UC Health for all claims, including negligent retention and credentialing brought by Plaintiff.
15. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to WCMC and UC Health pertaining to the claims against them. WCMC's and UC Health's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. WCMC and UC Health are both being referenced when only WCMC is named. I hold the following opinions relative to WCMC and UC Health pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani sought privileges prior to WCMC opening in May 2009 through May 2013 when he no longer had privileges. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:

FACTS

1. According to West Chester's first Executive Vice President, Carol King, she did not explore the "rumors" about Dr. Durrani's leaving Children's.
2. According to Carol King, the hospital tracked problem issues yet WCMC have failed to produce the information under peer review protection.
3. According to circulating nurse, Janet Smith, presets were changed in the computer to indicate the procedure Dr. Durrani performed after the procedure.
4. According to Janet Smith, despite no one at West Chester never working with Dr. Durrani before, WCMC never checked him out.

5. According to former University Hospital President (a UC Health hospital), Brian Gibler, hospitals face financial challenges.
6. According to risk manager, David Schwallie, risk management knew Durrani had issues.
7. According to radiologist, Thomas Brown, there were surgeons questioning Durrani's decisions to perform surgery.
8. According to medical staff director, Paula Hawk, a policy called "stop the lying" was implemented the same year and month they kicked out Dr. Durrani. This infers a poor environment of honesty and disclosure before this policy.
9. According to Paula Hawk and as the director of medical staff, money is not supposed to trump patient safety.
10. According to Paula Hawk, she admits peer review is for hospitals to protect each other.
11. According to Paula Hawk, she admits hospitals are interested in volume, something Dr. Durrani provided for WCMC and UC Health.
12. According to Mike Jeffers, the director of finance, they tracked Dr. Durrani's financial numbers.
13. According to Mike Jeffers, he admits Dr. Durrani helped them in their time of need.
14. According to Mike Jeffers, Dr. Durrani was the highest money generator.
15. According to Mike Jeffers, he knew Dr. Durrani had more than one surgical suite assigned at once.
16. According to Mike Jeffers, bonuses were paid to him and others based upon finances.
17. According to Dr. Peter Stern, he knew Dr. Durrani was only "satisfactory," not a world class spine surgeon as West Chester advertised.
18. Dr. Stern doesn't deny admitting UC Health looked the other way on Durrani because of money.
19. According to credentialing manager, Ann Shelly, there was plenty of "public knowledge" about Dr. Durrani to check before credentialing.

20. According to Ann Shelly, West Chester relied on the NPDB they knew was protected by hospitals.
21. Dr. Eric Schneeberger, Dr. Durrani's partner, was on the MEC at WCMC.
22. According to Eric Schneeberger, West Chester knew about Durrani scheduling surgeries long into the day and night.
23. According to former nursing manager, Elaine Kunko, WCMC knew about Dr. Durrani not completing records.
24. According to Elaine Kunko, WCMC knew Dr. Durrani would claim surgeries were emergency when they were not.
25. According to Elaine Kunko, WCMC knew there was an issue with Dr. Durrani not being in the room doing surgery on "his" patient.
26. According to Elaine Kunko, even the OR nurses knew WCMC put up with Dr. Durrani for money.
27. According to Elaine Kunko, WCMC tracked Dr. Durrani's financial numbers.
28. According to perioperative director, Lisa Davis, WCMC knew Durrani's office is supposed to get consents so WCMC had an obligation to make sure they did.
29. According to Jill Stegman, the risk manager at West Chester, she knew Durrani had "issues."
30. Jill Stegman confirms Gerry Goodman's complaints.
31. According to Kathy Hays, WCMC knew how Dr. Durrani used BMP-2 and PureGen.
32. Dr. Tim Kremchek, the Chief of the Orthopedic department, failed to do his job under the MEC bylaws as it related to the supervision and review of Dr. Durrani.
33. According to Dr. Tim Kremchek, he knew Dr. Durrani was "sloppy."
34. Kevin Joseph, the CEO of WCMC, claims to know nothing about surgery operations in his hospital.
35. Kevin Joseph, the CEO, claims a hospital must protect patients from unnecessary harm "as much as they can."

36. Kevin Joseph, the CEO, claims WCMC doesn't have oversight of surgeons doing what Plaintiff claims Durrani was doing. (Despite what his bylaws state.)
37. Kevin Joseph, the CEO, denies the hospital has any responsibility if Dr. Durrani did an unnecessary surgery.
38. Kevin Joseph, the CEO, despite his finance office tracking it, denies any knowledge of BMP-2 use.
39. Kevin Joseph, the CEO, denies knowing about any complaints about Dr. Durrani.
40. Kevin Joseph, the CEO, admits they benefited financially from Dr. Durrani, including his own pay.
41. Mark Tromba, the OR manager, admits BMP-2 use as used by Dr. Durrani.
42. According to Jeff Drapalik, the Senior Leadership team, including Joseph, met weekly and reviewed numbers.
43. According to Jeff Drapalik, the CFO of WCMC knew Dr. Durrani was a high volume money maker.
44. Lesley Gilbertson, a member of the MEC of WCMC, and anesthesiologist working with Durrani, had a concern about how long Durrani kept patients under.
45. According to materials manager, Dennis Robb, WCMC knew the volumes of BMP-2 being used.
46. According to Karen Ghaffari, WCMC knew the chart documentation of Dr. Durrani was not in compliance with their bylaws.
47. Patrick Baker, nursing VP at WCMC admits WCMC tracked the financial performance of Dr. Durrani.
48. According to nurse, Vicki Scott, the administration of WCMC knew from the outset of West Chester all the serious issues pertaining to Dr. Durrani.
49. According to Vicki Scott, West Chester's risk manager began to ignore complaints from Ms. Scott.
50. According to Vicki Scott, staff was scared to speak out.

51. According to Vicki Scott, patients didn't know who did the surgeries—Shanti or Durrani.
52. According to Vicki Scott, records were not accurate who was in the OR at what time.
53. According to Vicki Scott, everyone at WCMC knew it was about money.
54. According to Vicki Scott, WCMC knew about Dr. Durrani's and West Chester's illegal use of PureGen.
55. According to Vicki Scott, Dr. Durrani was a behavior problem.
56. According to patient representative, Elizabeth Dean, WCMC tracked Dr. Durrani's volumes from the outset and the CFO loved what he saw.
57. According to Elizabeth Dean, WCMC knew Dr. Durrani had issues at Children's.
58. According to Elizabeth Dean, WCMC knew Dr. Durrani was performing unnecessary procedures by volumes and repeats.
59. According to nurse, Scott Rimer, WCMC knew Dr. Durrani waited until after surgeries to document what procedures were planned.
60. According to Scott Rimer, patients at WCMC had procedures they did not consent to and WCMC knew it.
61. According to Scott Rimer, sterile fields were not protected.
62. According to Scott Rimer, WCMC knew PureGen was being used by Dr. Durrani and allowed it.
63. According to Thomas Blank, PureGen was an alternative to BMP-2, which WCMC turned to based upon insurance denials of BMP-2. In addition, Dr. Durrani operated an unethical POD of Alphatech called Evolution Medical to sell PureGen to West Chester.
64. According to Gerry Goodman, WCMC tracked BMP-2 use by Dr. Durrani; patients did not know who at times performed their surgery Dr. Shanti or Dr. Durrani; electronic records had to be changed after Dr. Durrani's surgery; Dr. Durrani and WCMC never obtained informed consents; Dr. Durrani's volume was a warning sign of overutilization. Gerry Goodman reported all these concerns to WCMC and there was no action. Gerry Goodman was told and concluded that WCMC did not want to do anything about Dr. Durrani because of money rewards.

ADDITIONAL OPINIONS

65. The Center of Advanced Spine Technologies (CAST) negligently supervised and retained Dr. Durrani, including by allowing Dr. Durrani to perform unnecessary procedures and surgeries; use BMP-2 and/or PureGen without appropriate consent; failing to disclose Dr. Shanti and others involvement in surgery; improper billing; changing the pre-op and post-op records to coincide when the surgery was not the surgery disclosed; and all other conduct detailed in the documents I reviewed.
66. WCMC, UC Health and CAST's motive for their actions and inactions towards Dr. Durrani was financial gain.
67. The MEC, administration and Boards of WCMC and UC Health failed to "govern the affairs of the Medical Staff."
68. The MEC, administration and Boards of WCMC and UC Health failed to enforce their rules upon Dr. Durrani as they were required to do.
69. The MEC, administration and Boards of WCMC and UC Health failed to provide oversight of Dr. Durrani as they were required to do.
70. The MEC, administration and Boards of WCMC and UC Health failed to properly evaluate Dr. Durrani.
71. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
72. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline Dr. Durrani including summary suspensions and revocation.
73. The MEC, administration and Boards of WCMC and UC Health failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
74. The MEC, administration and Boards of WCMC and UC Health ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
75. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.
76. The MEC, administration and Boards of WCMC and UC Health certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they

were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.

77. The MEC, administration and Boards of WCMC and UC Health failed to act on Dr. Durrani's failure in medical record documentation.
78. The MEC, administration and Boards of WCMC and UC Health failed to require Dr. Durrani to follow the rules for off label experimental procedures.
79. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including Dr. Shanti.
80. The MEC, administration and Boards of WCMC and UC Health allowed Dr. Durrani to do multiple surgeries at once.
81. WCMC and UC Health have refused to provide as privileged the peer review information from WCMC for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
82. Based upon all of the above, it's my opinion that WCMC and UC Health were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at WCMC under the standards of Ohio as detailed in the Brenda Shell's Response to Motion for Summary Judgment and this proximately caused harm to Plaintiff.
83. The facts support Bill Spivy's claim for negligence, battery, lack of consent and fraud.
84. As a result of the negligence and conduct of Dr. Durrani, CAST, West Chester and UC Health, Bill Spivy suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFIANT SAYETH FURTHER NOT

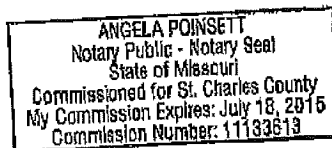


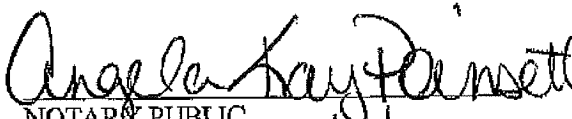
KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 13 day of ~~September~~ ^{October}, 2014.





NOTARY PUBLIC
My Commission Exp.: 07/18/2015
St Charles County
State of Missouri

**BILL SPIVY
AFFIDAVIT OF MERIT
CHRIST HOSPITAL**

I, Keith D. Wilkey, M.D., after being duly sworn and cautioned states as follows:

1. I devote at least one-half of my professional time to the active clinical practice in my field of licensure, or its instruction in an accredited school. I am an orthopedic surgeon whose focus is on spine surgery and treatment of those with spine issues.
2. I will supplement this affidavit with another, by a letter or by testimony, based upon any information provided to me after I execute it.
3. My curriculum vitae has been previously provided to opposing counsel in these Dr. Durrani cases and can be provided again upon request. For my review, I rely upon my education, training and experience.
4. I have not counted but I have reviewed, over 50 or more cases involving Dr. Durrani and the hospitals where he once had privileges.
5. I base my opinions in part on my review of all the cases I have reviewed which have revealed similar conduct by Dr. Durrani and the hospitals where he had privileges.
6. I am familiar with applicable standard of care for Ohio, Kentucky and the country for an orthopedic/spine surgeon such as Dr. Durrani.
7. I am also familiar with applicable standard of care, policies, rules and regulations, medical executive committee bylaws, JCAHO requirements, credentialing, supervising, retention of medical staff, granting and rejecting privileges and the peer review process for Christ Hospital (hereafter CH).
8. I have reviewed all relevant medical records including radiology of Dr. Durrani's medical treatment of Bill Spivy and the medical treatment of Bill Spivy at CH.
9. The Center for Advanced Spine Technologies, Inc. was Dr. Durrani's practice group and he was the sole owner, director and officer of CAST as well as an employee. CAST as such is also responsible for Dr. Durrani's negligence and for their failure to also supervise, discipline and retain Dr. Durrani.
10. I have also reviewed the nursing summary prepared by legal counsel's office for Bill Spivy. Based upon the number of cases I've reviewed pertaining to Dr. Durrani, legal counsel's office knows what materials I need to review and provides me those materials. In addition, while this affidavit contains case specific

information; it also contains information relevant to this case and/or many and/or most and/or all the other cases. It is prepared for me by counsel with my direction and approval like all of these have been.

11. Based upon my review, the following are the facts I rely upon:

- A. Billy Spivy was a 51 year old male when Dr. Durrani did the first of three surgeries. He is now a divorced and disabled 58 year old. Billy says he was an athlete when in high school and had always kept himself in fairly good condition. He states he use to run a lot on a daily basis and would run everywhere in the town he use to live in.
- B. Billy has a medical history of Hypertension, Hyperlipidemia, Coronary Artery Disease, CHF, Gout, Hypothyroidism, Anxiety and Bipolar Disorder. Surgically he has had operations on his hands, right foot, heart and neck.
- C. Billy use to manage a restaurant with his wife for several years had to be on his feet all day long which at the time was not a problem. He fell off of a two-story roof, back in 1991 and had lumbar surgery at that time at Vanderbilt. He did fine for about 15 years then the lower back pain returned along with right leg pain and right testicle pain. That's when he saw Dr. Durrani for an opinion. Billy's pain score 8-9/10 at this time.
- D. Billy states Dr. Durrani made the decision to operate at the first office visit and before he had even gotten the first MRI. It wasn't until after the surgery when Billy saw the x-ray films that he realized what he was feeling in his back was the hardware that had been put in place. Billy adamantly states Dr. Durrani did not explain to him about any of that hardware pre-operatively. (#1 Surgery - 2/9/07)
- E. 8/16/07 in an office note, Dr. Durrani stated that Billy was pretty happy with his progress and Billy states that has never been true. Billy continued with lower back and right leg pain and with the pain medication that Dr. Durrani continued to prescribe for him for two years. When he would question Dr. Durrani regarding the constant lower back pain and now neck pain also, Dr. Durrani would tell Billy the only thing that will help is more surgery.
- F. 8/31/07 in an office note, Dr. Durrani stated Billy was complaining of significant neck pain, left arm weakness, left arm numbness and the right leg is going numb as well. Apparently there was a period of time lapse because the next office note is 1/20/09 and again in an office note Dr. Durrani states Billy has severe cervical stenosis with intense symptoms. Dr. Durrani was so emphatic about more surgery he told Billy he would stop prescribing his pain medications unless he

agreed to more surgery. So Billy agreed to the cervical surgery (#2 surgery- 3/27/09) See diagnostic films of 3/27/09 below.

- G. Dr. Durrani had told Billy it would be about a 4-5" incision in his neck and it turned out to be about 10".
- H. At the time Billy states he didn't understand how neck surgery was going to help his lower back pain and when questioning never really got an answer from Dr. Durrani or the office staff. Billy says if the office staff answered any of his questions regarding himself, the next time he visited the office that person was no longer there.
- I. Billy had to have Cardiac Clearance and the Cardiologist, Dr. Raghu would not allow for the blood thinning medication to be stopped. (Dr. Raghu had been treating Billy for his CHF and had placed cardiac stents prior to the surgery.) Dr. Durrani assured Billy by not stopping the blood thinners would be no problem. Well that wasn't true because Billy did have an episode of excessive bleeding post-operatively resulting in receiving a unit of blood and increasing the hospital stay by 5 days. Apparently one of the nurses informed Billy that he had a TIA/heart attack during both #1 and #2 surgeries that he had not been aware of. He said when he questioned personnel at Christ no one would give a straight answer.
- J. Billy's pain continued in his lower back and down his right leg so he returned to Dr. Durrani again. Billy had to go back to Dr. Durrani because once other physicians found that he had surgery previously by Durrani they refused to get involved. So Dr. Durrani had informed Billy that he was well on his way of being totally disabled if he didn't have more neck surgery which came about, (#3 surgery - 9/17/10) Another complication ensued following that surgery which was MRSA. It took 2-3 months for that infection to clear up according to Billy. See cervical diagnostic report dated 6/25/10 below.
- K. Following this #3 surgery Billy had to go to see Dr. Tayeb for 12 epidural steroid injections to try to help ease his pain. Billy stated on many occasions Dr. Tayeb wasn't even able to inject into the correct spaces due to the amount of hardware in place. Dr. Tayeb told Billy he had the limit of injections and he would have to go his PCP, Dr. Sabir Quraishi, to get his pain medications from then on.

- L. Billy says comments made to him by personnel made him feel uncomfortable and he wondered about the competency of Dr. Durrani, i.e. Radiology staff commenting they knew who did his surgery acting like it was a funny thing; a nurse, Rosa, who had been a cardiology nurse, stated to Billy, he was just a guinea pig so-to-speak, and another nurse from Dr. Tayeb's office telling Billy all they were doing was killing him. Billy's faith and trust in Dr. Durrani began to weaken from that time.
- M. 11/16/10 in an office note, Dr. Durrani stated Billy was now having right leg pain, pain shooting down the right leg along with numbness and tingling. Billy had been complaining about this right leg pain and right testicle since the first office visit on 11/9/06. Dr. Durrani's impression of that visit was:
- Lumbar spinal Stenosis associated with lumbar spondylolisthesis L3-L4, L4-L5
 - S/P prior lumbar interbody fusion at L2-L3 and L5-S1
 - Progressive and severe symptoms of neurogenic claudication
 - Back pain with radicular pain in the L3-L4 and the L4-L5 distribution
 - Very significant functional impairment
 - Anterolisthesis of L3 on L4 and L4 on L5
 - Adjacent level degeneration L3-L4, L4-L5
 - Severe central stenosis L4-L5 and moderate central stenosis L3-L4
 - Severe foraminal stenosis bilaterally at L4-L5, moderate at L3-L4
 - Failure of conservative treatment for over many years.
- N. 2/28/11 Billy apparently had a cardiac arrest immediately following a cardiac stent placement and was resuscitated by cardiologist, Dr. Raghu.
- O. 10/2/12 In a letter to Billy's PCP, Dr. Sabir Quraishi, Dr. Durrani's stated Billy had returned with ongoing right leg pain along with it giving out on him without warning causing him to fall, 1-2X/week. Billy's forward flexion and extension both were painful. Dr. Durrani reminded Dr. Quraishi that Billy had failed cardiac clearance when he previously had Billy scheduled for lumbar surgery. His plan was to repeat a lumbar MRI and have Billy return to the office for a surgical decision. This #4 surgery was never done.
- P. Billy had been complaining to his PCP that he chokes easily and has difficulty swallowing and clearing his throat. Dr. Quraishi ordered a CT of the Neck. Billy was told by a Dr. Susan that the way he holds his head and neck from the neck surgery is crunching his Thyroid. He states he is able to palpate this which then makes him nauseated.

Q. 2/12/13 CT of the Neck with IV Contrast

Impression: * Mild dorsal protrusion of the right lobe of the Thyroid, otherwise unremarkable appearance of the thyroid. * Mild enlargement of an upper jugular lymph node of each side.

- Moderate diffuse mural thickening of the upper esophagus may indicate esophagitis or severe reflux. This should be evaluated further as clinically warranted.
- Other findings including enlargement of the ascending Aorta and bony findings.

Billy's last visit to Dr. Durrani was on 3/20/13.

R. Questionable if the correct procedure was done for #1 surgery. No office note regarding Dr. Durrani's decision as to why this surgery was done at this time.

S. Dr. Durrani's misinterpretation of the pre-operative diagnostic:

#1 Surgery - 11/9/06 Scoliosis Survey done @ University Pointe

Impression: Limited examination. Very mild scoliotic curvature at the thoracolumbar junction.

Multilevel degenerative discogenic changes. Suspected transitional segment at the lumbosacral junction, considered S1 for the purpose of this examination. (included)

#1 - Surgery - 4/12/07 Lumbosacral Spine @ Adams County Hospital

Findings: it is stated there has been unilateral posterior fusion at L2-L3 with right-sided pedicle screws and a vertical bar, hardware intact. There is asymmetric loss of disc space height at L2-L3 greater on the left, resulting in degenerative scoliosis. At L5-S1 disc space has been preserved and no subluxation. (included)

#1 Surgery - 4/21/10 Lumbosacral Spine series @ The Christ Hospital

Impression: 4 lumbar type vertebral bodies, status post posterior fusion L1- L2,

Prior anterior and posterior at L4-S1.

The Informed Consent does mention L1-L2 or L4.

The Informed Consent was signed for L2-L3 and L5-S1 percutaneous transforaminal lumbar interbody fusion for #1 surgery.

#2 Surgery - 8/23/07 - Cervical Spine MRI without Contrast

Impression: Post-fusion changes with diffuse posterior bulging of the fused vertebral bodies and mild narrowing of the canal at this level, other area of disc protrusion with areas of canal narrowing and mild cord volume loss. (included)

#2 Surgery - No other Radiology Reports available from 8/23/07 to the day of surgery on 3/27/09.

Page 14 is missing, but the Diag C-Spine 2-3 Views dated 3/27/09 @ Christ Hospital

Impression: Prior anterior fusion at C5-C7, Mild anterior bony spurring at C3-C4, moderate anterior bony spurring at C4-C5 and reversal of normal cervical lordosis. (included)

#2 Surgery procedure is questionable as to why it was done at that time.

#3 Surgery - 6/25/10 Cervical Spine MRI without Contrast @ Adams County Hospital

Findings: It is noted that C7-T1 is unchanged without significant canal narrowing. There is no significant foraminal narrowing. Comparison was 8/2007

#3 Informed Consent is missing. Three months later, the Op Report 9/19/10 states the procedures done were on C7-T1, anterior discectomy, fusion with Allograft and Autograft, cervical cage placement and instrumentation.

#3 Surgery procedure is questionable as to why it was done.

T. On the first office visit, Dr. Durrani recommended the first surgery.

U. Dr. Durrani performed three surgeries on this client:

#1 – Surgery – 2/6/07 @ The Christ Hospital

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Lumbar 2 –L3 Discogenic disease with stenosis
- L5 – S1 Discogenic disease with foraminal and central stenosis

PROCEDURES:

- L2-L3 Right foraminal decompression and laminectomy
- L2-L3 posterior spinal instrumentation
- L2-L3 posterior spinal fusion
- L5-S1 transforaminal lumbar interbody fusion
- L5-S1 Posterior spinal instrumentation
- L5-S1 Posterior spinal fusion

2 – Surgery – 3/27/09 @ The Christ Hospital

PREOPERATIVE POSTOPERATIVE DIAGNOSES: SAME

Cervical Spinal Stenosis

PROCEDURES:

- C3 thru C7, Posterior Cervical Laminoplasty with Left sided opening and Right sided hinging.

#3 – 9/17/10 – Surgery - @ West Chester Medical Center

PREOPERATIVE & POSTOPERATIVE DIAGNOSES: SAME

- Cervical Degenerative Disc Disease C7-T1

- Cervical Spinal Stenosis C7-T1
PROCEDURES:
- Anterior Cervical Discectomy C7-T1
- Anterior Cervical Fusion using Autograft and Allograft C7-T1
- Anterior Cervical Placement Interbody Cage C7-T1
- Anterior Cervical Placement Instrumentation C7-T1

V. BMP-2 was used during the following surgeries:

- #1 Surgery – Recombinant BMP
- #3 Surgery – BMP, Bioact Foam, Autograft and Allograft

W. The following hardware was implanted:

- #1 - Surgery - 2 – Screws 6.5x35mm - Medtronic
 - 4 – 6.5x45 mm - Medtronic
 - 6 – Set Screws – Medtronic
 - 2 – Rods 45mm – Medtronic
 - 1 – Rod 50mm – Medtronic
 - Master Graft Matrix
 - Capstone Verte-stack VBS 36x14mm
 - INFUSE Bone Graft Large Kit
 - #2 – Surgery - 3 – Plates 10mm - Medtronic
 - 18 – Screws 7mm - Medtronic
 - 2 – Plate 12mm – Medtronic
 - 1 – Screw 9mm – Medtronic
 - #3 – Surgery – 1- Foam Bioact Vitoss Pack 5cc – Orthovita
 - 1 – INFUSE XX Bone Graft 5m 0.7ml -0 Medtronic
 - 1 – SPCR Vert Lord Cr 9mm Polymer – Synthes Spine
 - 3 – Screws Cerv VA SD VECTRA 4x14 T1 – Synthes Spine
 - 2 – Screws Cerv VA SD VECTRA 4x16 T1 – Synthes Spine
 - 1 – Plate Cerv VECTRA 1 Lev 16mm T1 – Synthes Spine
 - 1 – SPCR VERT Lord CR 8mm Polymer – Synthes Spine
- X. Billy stated that Dr. Durrani did not explain to him that he was going to put in all that hardware, afterwards he was most upset because he had no idea until he saw his x-rays. He says the only thing he recalls was that he would have artificial disc inserted and had no concept of what it actually involved because Dr. Durrani had not explained it to him clearly.
- Y. Off-Label Use:
- #1 Surgery - was a TLIF approach
 - #2 Surgery - was a posterior approach.

#3 Surgery - was a standard right-sided Smith-Robinson approach.

Z. Operative Report Dictations:

#1 Surgery was dictated and verified by Dr. A. Durrani on 11/3/10 (47 days later).

#2 Surgery was dictated by Dr. A. Durrani on 3/30/09 (3 days later) and verified by Dr. Durrani on 6/10/09 (75 days later).

#3 Surgery was dictated and verified by Dr. A. Durrani on 11/3/10 (47 days later).

AA. The following consists of failed hardware:

#1 Surgery was going to be revised due to the continued leg pain only this time he was going to involve L4-L5, of which he skipped over on the first surgery.

BB. The client has not seen a subsequent treating physician, but Dr. Durrani had planned to do a revision of #1 Surgery – Lumbar but due to the patient's CHF he was not cleared by Cardiology for the procedure.

CC. The patient tried to see other surgeons (Mayfield Clinic) but once they found out Dr. Durrani had operated on him they refused to get involved.

DD. As Billy said it should go without saying that he has much more pain now than he ever imagined prior to Dr. Durrani's surgery. Billy states it's without a doubt that his life has been ruined by Dr. Durrani and he is not able to even do his daily living activities without help. Billy says he has now experienced what a 10 on the pain scale really is and that he has a 9-10/10 pain constantly since the first surgery. When the weather is bad his pain seems to be a 10/10 all day.

EE. Billy has had to move three times since original surgery because he then had trouble getting up and down the steps of his apartment. In the last 4 years Billy has become so debilitated from the constant pain and inability to walk. He's had to move into an assisted living nursing facility. He has an Aide that comes in every day to help him get his clothes on and get his meals for him. A nurse comes once a week for the CHF. Billy says sometimes he gets so depressed over the whole situation and having to tolerate the constant pain, he gets an occasional idea of why stick around but says he is not suicidal. His limitations are extensive these days such as:

Walking – before Durrani's surgery he use to walk everywhere for hours and now he can only manage to walk for less than 5 minutes. He walks with a cane or a walker. He states he continues to resist suggestions of utilizing a wheelchair cause he feels once he gives into it he may not be able to walk at all.

Bathing – he needs assistance with getting in and out of the shower, prone to falling of which he has frequently since his right leg continues to give out on him.

Dressing himself is a problem since he cannot raise his arms above his shoulders requiring him to have help in putting on tee shirts. When he forces himself to do this pain shoots up his neck and into his back. He suffers with headaches frequently. He is able to get his pants on but needs help in getting his shoes on.

Sitting- was not a problem before the 1st surgery but currently 15 minutes is maximum before he has to change his position.

Standing – was the usual routine since he ran a restaurant and was on his feet all day.

Laying down is limited to only his right side.

Sleeping – comes in shifts of 3 maybe 4 hours at a time then he has to get up and sit for brief period then go back to bed. At night his right leg seems to fall asleep which then awakens him.

Lifting – before all the surgeries was not a problem to lift whatever he needed to but currently is about 2-3 lbs at a time. If he attempts to pick up anything heavier he then pays for it with pain shooting up his back and neck resulting in a bad headache.

Household chores – he is not able to do on a daily basis, the Aide tends to all his needs in that aspect including mailing his bills.

Grocery shopping – the Aide does that for him also.

Flexion – of his neck is limited as well, he can turn his head a little to the right but not at all to the left. He can bend his neck forward just a little.

Shaving his neck requires assistance because he cannot bend his neck backwards.

Flexion – of his back is limited to being able to lean forward a little and is unable to bend over.

Driving – he does not do anymore because of the limited flexion of his neck, afraid he might run into another car.

FF. Billy seems to have accepted the fact he will have to live with the pain he endures every day for the rest of his life. He says at times it gets depressing. He has been told he will have to be on pain medications, muscle relaxants – Robaxin along with Neurotin and Baclofen for the rest of his life.

12. Based upon my review, the following are my **opinions** based upon a reasonable degree of medical certainty pertaining to the deviation in standard of care or negligence, informed consent, battery and fraud claims against Dr. Durrani and CH which proximately caused harm to Plaintiff:

- A. Need to have additional surgery to repair problems created by Dr. Durrani
- B. Implantation of BMP-2 without informed consent
- C. Failed hardware
- D. Failure to obtain proper informed consent for surgery

- E. Failure to provide adequate and thorough pre-operative and post-operative patient surgical education
- F. Failure to properly post-op monitor the patient
- G. Failure to properly perform follow up, post-op care
- H. Negligent surgical techniques
- I. Failure to maintain accurate and complete surgical records and surgical consent forms
- J. Failure to disclose important health information to patient
- K. Failure to maintain and complete discharge summary
- L. Failure to supervise Dr. Durrani
- M. Negligent pre-surgical diagnosis
- N. Failure to prepare a timely operative report or other medical record
- O. Billing for services not completed
- P. Not informing the patient another surgeon will be doing all or part of the surgery
- Q. Practicing outside Dr. Durrani's scope of training, education, experience, and Board certifications
- R. Deviation in standard of care
- S. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- T. Failure by Dr. Durrani to inform patient of additional/changed procedure and reason
- U. Failure by CAST to disclose additional/changed procedure and reason to patient
- V. Failure by Dr. Durrani at CAST to properly educate patient regarding diagnosis
- W. Prior knowledge of possible complication and not acting properly upon same

- X. Failure to disclose pertinent health information to another health care provider
- Y. Fraudulent, negligent and reckless pre-operative work up
- Z. Fraudulent, negligent and reckless surgery
- AA. Inaccurate, fraudulent, and/or exaggeration of diagnoses
- BB. Failure to properly educate patient regarding diagnoses
- CC. Failure to attempt non-surgical conservative treatment
- DD. Failure to perform thorough and accurate pre-op nonsurgical evaluation
- EE. Failure by Dr. Durrani at CH to perform accurate and complete preoperative teaching
- FF. Failure by Dr. Durrani at CH to properly educate patient regarding diagnoses
- GG. Failure by Dr. Durrani at CH to maintain accurate and/or complete medical records
- HH. Failure of informed consent by Dr. Durrani at CH
- II. Failure of CH to insure Dr. Durrani and CAST had obtained proper informed consent
- JJ. Failure of CH to obtain proper acknowledgement of consent
- KK. Failure by Dr. Durrani at CH to disclose pertinent health information
- LL. Failure by CH to disclose additional/changed procedure and reason to patient
- MM. Failure by CH to supervise staff
- NN. Failure by CH staff to properly document abnormalities and follow up care
- OO. Non-approved hardware combinations
- PP. Dr. Durrani made false and material misrepresentations of material facts intended to mislead Bill Spivy and concealed material facts he had a duty to disclose. CH and CAST concealed material facts they had a duty to disclose. Bill Spivy was justified in relying on the misrepresentation and did rely

proximately causing harm to Bill Spivy. Dr. Durrani and CH intentionally misled Bill Spivy. Bill Spivy had the right to correct information.

13. Based upon my review of the deposition testimony, the JCAHO requirements, the MEC bylaws and all the information provided to me, I am able to adopt the following opinions relating to CH pertaining to the claims against them. CH's actions and inactions detailed in this affidavit proximately caused harm to Plaintiff. CH are both being referenced when only CH is named. I hold the following opinions relative to CH pertaining to their conduct acting through their administration and MEC. The time period covered is from the time Dr. Durrani joined CH until he left by August 2013. In addition to my opinions, I set forth facts I rely upon. This includes all which I referenced that I reviewed. In addition to all of the above, I attest to the following:
 1. CH's motive for their actions and inactions towards Dr. Durrani was financial gain.
 2. The MEC, administration and Boards of CH failed to "govern the affairs of the Medical Staff."
 3. The MEC, administration and Boards of CH failed to enforce their rules upon Dr. Durrani as they were required to do.
 4. The MEC, administration and Boards of CH failed to provide oversight of Dr. Durrani as they were required to do.
 5. The MEC, administration and Boards of CH failed to properly evaluate Dr. Durrani.
 6. The Orthopedic and Surgery Departments abdicated their responsibility under the MEC bylaws to review, investigate and supervise Dr. Durrani.
 7. The MEC, administration and Boards of CH failed to properly discipline Dr. Durrani including summary suspensions and revocation.
 8. The MEC, administration and Boards of CH failed to properly discipline under the MEC bylaws as it pertains to Dr. Durrani.
 9. The MEC, administration and Boards of CH ignored the information readily available pertaining to Dr. Durrani before credentialing and granting him privileges.
 10. The MEC, administration and Boards of CH failed to act on Dr. Durrani's disruptive behavior, unprofessional behavior and clinical performance placing Plaintiff at risk.

11. The MEC, administration and Boards of CH certified and approved the unnecessary procedures of Dr. Durrani on Plaintiff knowing they were unnecessary and knowingly allowing the improper use of BMP-2 and/or PureGen and knowing there was not proper informed consent.
12. The MEC, administration and Boards of CH failed to act on Dr. Durrani's failure in medical record documentation.
13. The MEC, administration and Boards of CH failed to require Dr. Durrani to follow the rules for off label experimental procedures.
14. The MEC, administration and Boards of CH allowed Dr. Durrani to use undisclosed and unqualified surgeons to perform his surgeries including fellows and interns.
15. The MEC, administration and Boards of CH allowed Dr. Durrani to do multiple surgeries at once.
16. CH have refused to provide as privileged the peer review information from CH for Dr. Durrani to either me or their own expert. Therefore, we have no knowledge of what action, if any, was taken against him. However, based upon the facts here, it is obvious they failed to take action.
17. Based upon all of the above, it's my opinion that CH were negligent in their credentialing, supervising, disciplining and retaining Dr. Durrani on staff and allowing him to obtain and keep privileges at CH under the standards of Ohio and this proximately caused harm to Plaintiff.
18. The facts support Bill Spivy's claim for negligence, battery, lack of consent and fraud.
19. As a result of the negligence and conduct of Dr. Durrani and CH Bill Spivy suffered damages proximately caused by them, including the following:
 - A. Permanent disability
 - B. Physical deformity and scars
 - C. Past, Current and Future Physical and Mental Pain and Suffering
 - D. Lost income past, present and future
 - E. Loss of enjoyment of life
 - F. Past medical expenses
 - G. Future medical expenses approximately in the amount of \$50,000 to \$250,000 depending on course of treatment
 - H. Aggravation of a pre-existing condition
 - I. Decreased ability to earn income
 - J. 3% increased risk of cancer and fear of cancer if BMP-2 was used.

AFFLIANT SAYETH FURTHER NOT

K Wilkey M.D.

KEITH D. WILKEY, M.D.

NOTARY

SUBSCRIBED, SWORN TO AND ACKNOWLEDGED before me, a Notary Public, by

Keith D. Wilkey, M.D. on this 13 day of October, 2014.

Angela Kay Poinsett

NOTARY PUBLIC

My Commission Exp: 07/18/2015

St. Charles County

State of Missouri

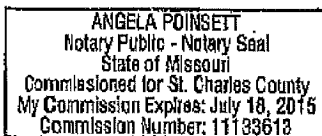


EXHIBIT A

SANTEN & HUGHES
M E M O R A N D U M

TO: John
FROM: Sandy
DATE: August 6, 2010
RE: Brenda Shell

I spoke with Brian with the West Chester Medical Center today who advised that Dr. Durante still has not signed off on the op reports. He said Dr. Durante is currently suspended and cannot schedule new patients, surgery, etc. until his charts are completed so he is hopeful he will get the reports signed soon. I will call back in a couple of weeks.

TO: John
FROM: Sandy
DATE: September 21, 2010
RE: Br nda Shell

I spoke with Brian again at the West Chester Medical Center who advised that Dr. Durante still has not signed off on the op reports. He advised that he has talked to Dr. Durante's office and they are aware that he needs to sign the reports. He said there is nothing else he can do and suggested I continue to call him for the status. I will call back in a couple of weeks.

TO: John Shell File
FROM: John Holschuh
DATE: October 5, 2010

Talked with Brian at West Chester on October 5. He advised Durante still has not signed on two places in the chart. Apparently he said the higher echelon at the hospital has been on it and they are doing everything they can to get Durante to sign. His privileges are still suspended until he signs. In any event, I called Brian a second time and told him that we understood that the records had been released to the insurance company. He said they can release the records to the insurance company unsigned because it is for billing purposes as opposed to legal purposes. I told him that at this point we just need to get the records even if they are not signed and notarized. He said he would go ahead and process this and get the records to us with that understanding.

cc: Mr. John Shell

EXHIBIT B

1. Dr. Durrani suspended some time sooner than August 6, 2010 through at least October 5, 2010.
2. What surgeries performed during that time?

Bartlett, Cindy	WCH	08/02/10
Slone, Crystal	GOOD SAM	08/06/10
Rose, Dorothy	WCH	08/08/10
Couch, Jackie	WCH	08/11/10
Stanfield, Rick	WCH	08/13/10
Underwood, Connie	WCH	08/13/10
McQueary, Tonia	WCH	08/16/10
Smith, Donald	GOOD SAM	08/20/10
Botner, Gerald	WCH	08/23/10
Houghton, Robert	WCH	08/23/10
Ross, Carol	WCH	08/25/10
Rowley, Ronald	WCH	08/25/10
Brady, Rebekah	WCH	08/27/10
Allen, Sherry Lynn	WCH	08/30/10
Kallmeyer, Ward, Linda	WCH	08/30/10
Johnson, Chelsea	GOOD SAM	09/03/10
Rosebery, Faye	WCH	09/08/10
Shempert, David	WCH	09/10/10
Bachmann, Gayle	WCH	09/15/10
Juergens, Sarah	WCH	09/15/10
Quinn, Marcia	WCH	09/17/10
Rodriguez, Debbie	WCH	09/17/10
Spivy, Billy	WCH	09/17/10
Bradshaw, Latoya	WCH	09/20/10
Koch, Amanda	WCH	09/20/10
Atwood, Christopher	WCH	09/22/10
Favaron, Neil	WCH	09/22/10
Kauffman, Katelyn	WCH	09/22/10
Goldstein, Christine	WCH	09/24/10
Ray, Todd	WCH	09/29/10
Hickey, Jennifer	WCH	10/01/10
Hursong, Carolyn	WCH	10/01/10
Shempert, David	WCH	10/01/10
Stratman, Sierra	GOOD SAM	10/01/10

Bayliss, Steve (Louise)	WCH	10/04/10
Kallmeyer, Ward, Linda	WCH	10/04/10
Marksberry, Paul	WCH	10/04/10
McCauley, Hiram	WCH	10/04/10